

FILED

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

U.S. DISTRICT COURT
DISTRICT OF RHODE ISLAND

AMERICAN SALES COMPANY, LLC,
on behalf of itself and all others similarly
situated,

Plaintiff,

v.

WARNER CHILCOTT PUBLIC LIMITED
COMPANY, WARNER CHILCOTT
COMPANY, LLC, WARNER CHILCOTT
HOLDINGS COMPANY III, LTD.,
WARNER CHILCOTT CORPORATION,
WARNER CHILCOTT (US), LLC,
WARNER CHILCOTT SALES (US), LLC,
WARNER CHILCOTT LABORATORIES
IRELAND LIMITED, WARNER
CHILCOTT COMPANY, INC., WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., ACTAVIS, INC.,
LUPIN LTD., LUPIN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. _____

CA 13- 347M

CLASS ACTION COMPLAINT AND JURY DEMAND

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Plaintiff American Sales Company, LLC on behalf of itself and all others similarly situated, for its complaint brought under Section 4 of the Clayton Antitrust Act, 15 U.S.C. § 15, and Rule 23 of the Federal Rules of Civil Procedure against Defendants Warner Chilcott Public Limited Company, Warner Chilcott Company, LLC, Warner Chilcott Holdings Company III, Ltd., Warner Chilcott Corporation, Warner Chilcott (US), LLC, Warner Chilcott Sales (US), LLC, Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., Actavis, Inc., Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., allege as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

I. INTRODUCTION

1. Few things are certain in patent law. But everyone agrees that an invention in public use more than a year before an inventor applies for a patent is not patentable. And that an invention has to actually do what you say it does in order to be protected by a patent.

2. This is a civil antitrust action seeking treble damages arising out of the defendants' scheme to unlawfully allocate the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo), that Warner Chilcott sells under the brand name Loestrin 24 Fe (also referred to as "Loestrin 24").

3. Warner Chilcott has sold oral contraceptive products bearing the "Loestrin" name in the United States since 1973. All of the Loestrin products include "active" pills containing norethindrone acetate and ethinyl estradiol, intended to prevent pregnancy; some include placebo pills, some do not.

4. In the early 1990's, scientist Gary Hodgen conducted studies using the active pills from Loestrin 1/20 at the Eastern Virginia Medical School. In one study of thirty women,

Hodgen compared incidents of breakthrough bleeding in women who took Loestrin 1/20 pills for 24 days to the incidence of breakthrough bleeding in women who took Loestrin 1/20 pills for the recommended 21 days. Hodgen found no significant differences in the incidence of breakthrough bleeding.

5. Despite the lack of differences in the incidence of breakthrough bleeding in Hodgen's human trial, Hodgen set out to obtain a patent for an oral contraceptive regimen with similar amounts of the same hormones contained in Loestrin 1/20 that decreased the incidence of breakthrough bleeding. To support his application to the Patent and Trademark Office (PTO), Hodgen cited data from a study done in two groups of five monkeys who took reformulated, adjusted versions of Loestrin 1/20 for 21 days and 24 days, respectively, that ostensibly showed a decrease in the incidence of breakthrough bleeding in cycles 2 and 3 – as would be expected. Hodgen never disclosed the existence of his human study, let alone the negative results, to the PTO. Nor did Hodgen disclose prior art that disclosed taking oral contraceptives for more than 21 days. Hodgen also represented to the PTO that no commercially available oral contraceptives contained more than 30 mcg of ethinyl estradiol while knowing full well that Loestrin 1/20 contained only 20 mcg.

6. In 1996, knowing nothing of these misrepresentations and omissions, the PTO issued a new patent for an oral contraceptive regimen containing similar amounts of the same hormones in earlier Loestrin products where active pills are taken for 24 days, instead of 21 days, in order to decrease the incidence of breakthrough bleeding – U.S. Patent No. 5,552,394 (the “'394 Patent”). But for Hodgen's wrongdoing, the '394 Patent would never have issued.

7. In 2006, the FDA approved a product with the same active pills as Loestrin 1/20 given for 24 days – ostensibly the commercial embodiment of the '394 Patent. The FDA noted

that the data provided by Warner Chilcott did *not* show a clinically meaningful reduction in the incidence of breakthrough bleeding as between women who took the Loestrin 1/20 pills for 21 days and women who took the Loestrin 1/20 pills for 24 days. The FDA nevertheless approved the product (marketed as Loestrin 24) but warned Warner Chilcott not to make comparative claims.

8. Warner Chilcott listed the '394 Patent – and only the '394 Patent – in the FDA's Orange Book as covering Loestrin 24 or a method of using Loestrin 24. The active ingredients in Loestrin 24, norethindrone acetate and ethinyl estradiol, are not protected by any patent.

9. Predictably, generic manufacturers applied for FDA approval to sell generic versions of Loestrin 24. Two generic manufacturers, Watson and Barr, already sold generic versions of all of the first generation Loestrin products. Meaning, Watson and Barr already manufactured and sold the same active pills used in Loestrin 24 in their versions Loestrin 1/20.

10. Both Watson and Barr announced their intention to come to market before the expiration of the '394 Patent. The '394 Patent claims only a narrow method of using active ingredients that have been employed for decades as oral contraceptives. Generic manufacturers knew the '394 Patent was invalid and/or unenforceable, and that their products did not infringe.

11. When faced with the prospect of imminent generic competition to Loestrin 24, Warner Chilcott paid the generic manufacturers, defendants Watson and Lupin, to withdraw their challenges to the '394 Patent and agree to stay out of the market for more than four years. Warner Chilcott then used that temporary absence of generic competition 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.

12. To implement its plan to prevent generic competition, Warner Chilcott sued generic drug manufacturers that submitted applications to the FDA for approval to sell generic versions of Loestrin 24, asserting that the generics infringed the '394 Patent. Warner Chilcott's purpose in filing the lawsuits was not to win, but to pave the way for entering into anticompetitive "settlement" agreements where they shared their monopoly profits with the generics in exchange for the generics' agreement to stay off the market. Under the Hatch-Waxman Act (discussed below), the mere filing of these lawsuits prevented the FDA from approving the generic drug applications 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.

13. Warner Chilcott knew it would lose the patent cases if they were litigated to conclusion (or even to summary judgment). So, as the 30-month stay against the first potential generic competitor Watson neared expiration, Warner Chilcott paid Watson to withdraw its patent challenges and delay entry into the market. In exchange for substantial payments from Warner Chilcott – in the form of a promise to forgo selling its own generic product – Watson agreed to stay out of the market until January 2014 – just six months before the '394 Patent is to expire.

14. Warner Chilcott repeated this tactic with the second potential generic competitor, Lupin. Knowing it would lose its '394 Patent infringement case against Lupin if it was litigated to conclusion, Warner Chilcott again agreed to share some of the monopoly profits with its potential competitor. In exchange, Lupin agreed to withdraw its challenge to the patent and delay entry until July 2014 - six months after Watson.

15. Having literally bought itself more time without generic competition, Warner Chilcott used that time to further extend its monopoly beyond the expiration of the '394 Patent in July 2014. Warner Chilcott is currently engaged in a "product hop," whereby it is converting the market for Loestrin 24, which will face generic competition beginning in January 2014, to a follow-on branded product that is ostensibly patent protected until February 2029. Warner-Chilcott's follow-on product is called Lo Loestrin Fe (also referred to as "Lo Loestrin").

16. Lo Loestrin provides no medical, convenience, or other benefit to patients over Loestrin 24. Scientific studies have shown that women have a 60% greater chance of becoming pregnant while taking Lo Loestrin as compared to Loestrin Fe. Nevertheless, beginning in January 2011, Warner Chilcott began marketing Lo Loestrin as superior to Loestrin 24, urging physicians to prescribe the follow-on drug instead of the older one.

17. It is well-established in the pharmaceutical industry that unless a brand manufacturer launches its follow-on product before entry of a generic version of the original product, it is unlikely to launch at all. As a result of state substitution laws and other institutional features of the pharmaceutical industry, once generic entry occurs, purchases of generic versions of a brand drug rapidly and substantially replace purchases of the brand drug, making any effort to "hop" sales from the original branded product to a follow-on branded product economically unfeasible. Thus, absent the unlawful payments by Warner Chilcott, and Watson and Lupin's agreement to stay off the market, Warner Chilcott would not have begun selling Lo Loestrin.

18. But for the anticompetitive scheme and agreements, a generic version of Loestrin 24 would have been available by September 2009, when the FDA would have granted final approval to Watson's generic Loestrin 24. Other generic versions of Loestrin 24, including an authorized generic version marketed directly or indirectly by Warner Chilcott, would also have

entered, driving generic prices down to near marginal cost. Plaintiff and the members of the Class would have substituted the generic products for their purchases of branded Loestrin 24. Absent the anticompetitive scheme and agreements, Warner Chilcott would not have been able since January 2011 to substantially reduce the number of Loestrin 24 prescriptions available for generic substitution by effecting the product hop to Lo Loestrin.

19. Through anticompetitive scheme and agreements, defendants violated Sections 1 and 2 of the Sherman Act, improperly foreclosing competition for lower priced versions of generic Loestrin 24.

II. PARTIES

20. Plaintiff American Sales Company, LLC (“American Sales”) is a Delaware limited liability company with its principal place of business in Lancaster, Erie County, New York. American Sales brings this action on its own behalf and as an assignee of McKesson Corp. which, during the class period, purchased Loestrin 24 directly from Warner Chilcott, and as a representative of all entities similarly situated. American Sales was injured as a result of the defendants’ anticompetitive scheme.

21. Defendant 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.

22. Defendant 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.

This defendant is a wholly owned subsidiary of Warner Chilcott PLC.

23. Defendant 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.

24. Defendant Warner Chilcott Corporation is a corporation organized and existing under the laws of Delaware, having its principal place of business at 100 Enterprise Drive, Rockaway, New Jersey 07866.

25. Defendant 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. Defendant Warner Chilcott Sales (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.

27. Defendant 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.

28. Defendant 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.

29. The foregoing defendants are collectively referred to herein as “Warner Chilcott.” Warner Chilcott is engaged in the worldwide marketing, production, and distribution of pharmaceutical products, including in this district.

30. Defendant 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.

31. 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.

32. 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.

33. Defendant 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.

34. Defendant 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 400 051, India.

35. Defendant Lupin Pharmaceuticals Inc. is a corporation organized and existing under the laws of Virginia, having its principal place of business at Harbor Place Tower, III South Calvert Street, 21st floor, Baltimore, Maryland 21202. Lupin Pharmaceuticals Inc. is a wholly-owned subsidiary of Lupin Ltd.

36. Defendants 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.

37. Defendants Watson and Lupin are referred to collectively as the “generic defendants.”

38. All of the 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 the defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of the 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 the defendants.

III. JURISDICTION AND VENUE

39. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys’ fees for the injuries sustained by American Sales and members of the class (defined below) resulting from the defendants’ unlawful foreclosure of the United States market for Loestrin 24. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

40. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, the defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

41. Defendants' conduct, as described in this complaint, were within the flow of, were intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

42. During the class period, Warner Chilcott manufactured, sold and shipped Loestrin 24 in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

43. During the class period each defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

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

IV. REGULATORY BACKGROUND

45. Drug companies can, and do, obtain patents that cover their new prescription drug products. Those patents – when valid – provide a limited protection from competition by other drug companies for a fixed period of time.

46. The health and welfare of millions of Americans depends on access to safe, effective, and affordable medications. Modern medicine treats chronic conditions and prevents serious illnesses with maintenance prescription drugs – drugs that are taken for many months or

years. The high cost of drugs can mean no treatment, or inadequate treatment, for many.

Affordable drugs lead to better treatment and prevention.

47. By the same token, the American pharmaceutical industry is a business.

Companies that sell brand name drugs should be able to recoup their research and development investment, cover their marketing costs, and turn a reasonable profit for their shareholders.

48. At root, then, in the American system of access to prescription drugs is a basic principle – a rule of the road that addresses these goals and paves the way for more affordable drugs. It is this:

49. On the one hand, during the term of a legitimate patent, only the brand name drug company may sell its brand name drug. But once that patent expires, or the drug “goes off patent,” generic manufacturers can sell less expensive generic products that the FDA has approved as being “the same as” the brand. Put differently, brand names have a statutory period of time, but only that period of time, to charge very high prices for medications that, in fact, cost little to manufacture. Once the lawful periods of exclusivity expire, generic companies may get FDA approval as being the “same as” the brand, and the generic companies are free to manufacture generic products that are just as safe, just as effective, but far less expensive than the brand. The medication, then, becomes affordable for all, and the health and welfare of the system is no longer burdened by the high cost of the drug.

50. This case involves a breach by one large branded drug company, Warner Chilcott, and multiple generic drug companies with respect to this basic rule.

A. The regulatory structure for approval of new drugs.

1. Brand companies submit New Drug Applications.

51. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), drug companies who wish to sell a new drug product must file a New Drug Application (“NDA”) with the FDA.¹ An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.²

52. The FDA does not ordinarily test new drug products itself. Rather, the FDA requires manufacturers to test their own products and report the results; the FDA then closely analyzes the tests, test methods, and data/results provided by the manufacturer to confirm that the manufacturer has sufficiently shown the drug to be safe and effective.

53. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling.³

54. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements; namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

2. Patents covering branded drugs may be listed in the Orange Book.

55. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA publishes a list of

¹ 21 U.S.C. §§ 301-392.

² 21 U.S.C. § 355(a) and (b).

³ 21 U.S.C. § 355(d).

those patents in the publicly available “Orange Book.” Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance.⁴

56. The FDA relies completely on the manufacturer’s truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer’s representations. The FDA performs only a ministerial act in listing the patents identified by the manufacturer in the Orange Book.

B. Generic equivalents take sales from corresponding brand-name versions.

57. Because AB-rated generics are priced significantly below their branded counterparts, and other institutional features of the pharmaceutical marketplace, generic versions are liberally and substantially substituted for their brand-name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generically-equivalent product for the brand-name product prescribed, unless the doctor has indicated that the prescription for the brand-name product must be “dispensed as written.” Similarly, insurance plans often require or incentivize such substitution. As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease, and thus the loss of sales volume by the brand-name drug to the corresponding generic accelerates further. The price of the competing brand product predictably falls too.

58. Until a generic manufacturer enters the market, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand-name drug, and therefore the brand-name manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand-name sales. Consequently, brand-name drug manufacturers

⁴ 21 U.S.C. § 355(b)(1) and (c)(2).

have a strong incentive to use various tactics, including exclusion payment agreements such as the agreements discussed below, to delay the introduction of generic competition into the market.

59. Generic competition benefits all members of the proposed Class by enabling them to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand-name drug at a reduced price. Defendants' anticompetitive conduct blocked generic competition and injured plaintiff and the Class.

C. The regulatory approval process for generic drugs.

1. The Hatch-Waxman Amendments sought to expedite introduction of generic drugs.

60. In 1984, Congress passed the Hatch-Waxman Amendments to the Food Drug and Cosmetic Act.⁵ The Hatch-Waxman Amendments were "designed to speed the introduction of low-cost generic drugs to market" by permitting generic manufacturers to file abbreviated new drug applications (ANDAs)⁶ that rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – is that two drug products that contain the same active pharmaceutical ingredient, in the same dose, delivered in the same way, and are absorbed into the blood stream at a similar rate over a similar period of time are expected to be equally safe and effective. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other

⁵ Hatch-Waxman was an amendment to the Federal Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301-392. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (hereafter, the "Act"). See ¶¶47, 50. The regulatory scheme and associated incentives is set forth in the complaint at ¶¶47-70.

⁶ See Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

things, permitting a brand company to file a legitimate patent infringement lawsuit against a generic before the generic actually brought its product to market.

61. 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 name pharmaceutical companies. 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, with generic drugs accounting for 18.6% of prescriptions. By 2012, total prescription drug revenue had soared to over \$325 billion, with generic drugs accounting for 84% of prescriptions.

2. Generics can send Paragraph IV certifications to challenge patent coverage.

62. The Hatch-Waxman Act also create a mechanism intended to resolve patent disputes between brand and generic manufacturers before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Act permitted a brand manufacturer to sue a generic for patent infringement even if their products had not launched yet.

63. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. A generic manufacturer can make one of four certifications:

- i. that no patent for the brand name drug has been filed with the FDA;
- ii. that the patent for the brand name drug has expired;
- iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or
- iv. that the patent for the brand name drug is invalid or will not be infringed

by the generic manufacturer's proposed product.

64. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer can sue the ANDA applicant for patent infringement. If the brand name 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 thirty months, or (b) the entry of a final judgment on 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 go to market with its product. The 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.

65. The brand could file patent infringement claims more than 45 days after receiving the Paragraph IV certification, but doing so would not trigger the automatic stay of approval.

3. The first ANDA filer is, ordinarily, entitled to 6 months of exclusivity.

66. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, Hatch-Waxman Amendments gave the first generic manufacturer to file an ANDA containing a Paragraph IV certification a period of protection from competition with other generic manufacturers. 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 a second generic manufacturer will not be able to launch its own generic product for at least six months after the first launches.

67. 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 pharmaceutical companies to conspire 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 products.

68. Under the "failure to market" provision, a first ANDA applicant will forfeit its 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.

D. Brand companies have learned how to exploit the Hatch-Waxman regulatory framework.

69. While the Hatch-Waxman Act was "designed to speed the introduction of low-cost generic drugs to market," drug companies have learned how to exploit provisions of the Act in ways that frustrate congressional intent and violate antitrust laws.

1. Brand companies sometimes list invalid or inapplicable patents in the Orange Book.

70. A brand company has the ability to (illegally) list patents in the Orange Book that are either invalid, unenforceable, or do not actually cover the drug product. Listing these patents creates a pretext for filing a baseless infringement suit against generics who file Paragraph IV certifications.

2. Brand companies sometimes file baseless lawsuits just to trigger the 30-month stay.

71. Brand companies have the ability to (illegally) file a baseless patent infringement suit – a suit that the brand company will eventually lose – within 45 days of receiving a Paragraph IV certification triggers the 30-month stay of generic approval.

72. That brand-name 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.

3. Brand companies sometimes enter into reverse payment settlement agreements.

73. Hatch-Waxman encourages would-be generic companies to challenge weak or invalid patents. Following expiration of a 30-month stay of FDA ANDA approval (triggered by the brand company's suit in response to an ANDA), the Act permits "at risk" launch by generics, *i.e.*, generic launch prior to expiry of patents declared by the brand company to cover the brand drug. Hatch-Waxman incentivizes generics facing weak patents to market their products even while patent litigation is pending.

74. But the economic effect of the monopoly-to-commodity transition upon generic entry motivates perverse drug company schemes. In reverse payment agreements, the brand company pays or compensates the would-be generic maker to stay off the market. A generic may sometimes make more money accepting cash or other consideration from the brand and agreeing not to compete, than by pursuing and winning patent litigation or making an "at risk" launch even when the risk is minimal or nonexistent.

a. Reverse payment agreements often include bottlenecking settlements with the first-filer generic.

75. To encourage generic entry and challenges to brand patents, the Act affords the first ANDA filer who challenges the validity or coverage of the brand maker's patents a major economic benefit – for 180 days following the first filer's launch of its generic product, no other ANDA filer can come to market. With one exception (addressed momentarily), subsequent ANDA filers must wait for FDA ANDA approval for six months following the date the first filer chooses to launch its product. So the sooner the first filer launches, the sooner it enjoys six months free of competition from other ANDA-approved generics on the market (yielding substantial revenues), and the sooner the later-filed ANDAs may be approved.

76. But some reverse payment agreements reverse the impacts of these provisions. Brand companies pay off the first filer by having it both delay its initial launch (and get a cut of the brand maker's monopoly profits) and save the 180-day exclusivity for later use. The brand gets delay, and the first filer keeps exclusivity. The effect, however, is to delay not only the first filer's entry, but all later would-be generics, causing a "bottleneck" for later ANDA approvals.

b. Reverse payment agreements often include agreements to obstruct triggering the first filer's 180-day exclusivity.

77. Hatch-Waxman has an exception to the requirement that later ANDA filers must await the first filer's chosen launch date – the log jam is broken when final court decisions find that all patents listed in the FDA's Orange Book by the brand company as covering the drug are invalid or not infringed. But some brand drug makers strategically sue on some, but not all, applicable patents; challenges to those non-asserted patents must be made by the later-filed generics in often lengthy difficult declaratory judgment actions. The resultant procedural complexity delays, in turn, the later would-be generics' ability to get rulings, and then approval.

And by ultimately cutting a reverse payment deal with the later-filed generics, the brand can thwart entirely the potential for breaking the bottleneck.

c. Reverse payment agreements often include agreements not to launch an authorized generic.

78. When a would-be first generic finally does enter the market, it has become commonplace for the brand maker to launch a competing generic too (marketing under its NDA approval, hence the expression “authorized” generic). The near simultaneous launch of two generics (the would-be generic’s “real” generic and the branded company’s authorized generic) forces downward the price of both products, benefitting all purchasers but sharply cutting into the profits the first-filer would have made otherwise. An FTC study, for example, has found that the exclusivity period is extremely valuable to a generic and the presence of an AG can reduce the first ANDA filer’s sales by 50%.

79. But brand companies use the right to launch an authorized generic as a powerful tool to induce the first filer generic to delay its entry. If the parties shape the payment to the first filer as an agreement not to launch an authorized generic during the 180-day exclusivity period, the payment by the brand maker is not only just as good as cash, the increased revenues come from payments made by purchasers in the anticompetitive environment created by delaying entry of the authorized generic. Reverse payments in the form of authorized generic forbearance cut competition with both sides of the blade.

80. In an increasing number of instances, brand companies disguise an exclusion payment to a first-filing generic company by agreeing not to launch an “authorized generic” version of the branded drug during the first-filing generic company’s initial 180-day marketing exclusivity period. An authorized generic is the branded drug, manufactured just like the branded product, but sold as a generic product under the same approval as the brand product’s

original NDA. Because the brand manufacturer already has approval to sell its branded drug, it does not need to file an ANDA, or obtain any additional approvals, to market an identical version of the drug in a different package.

81. An authorized generic is the only other generic that can be sold during the first filer's 180 days of exclusivity.

82. For the generic manufacturer holding a 180-day exclusivity period, an authorized generic launch has a substantial impact on revenue. Generic companies generally make about 80% of their total profit on a given generic product during the 180-day exclusivity period, and an authorized generic, when launched during the 180-day exclusivity period and priced competitively, should capture half of total generic sales during that period. Freedom from an authorized generic during the initial 180-day period is thus exceedingly valuable to the generic company holding that exclusivity – it doubles the revenues and profits of that generic company.

83. To prevent this loss of revenue to an authorized generic launch, a generic company holding a 180-day exclusivity can profitably delay its entry in return for a brand company's agreement to forebear from launching an authorized generic during the 180-day exclusivity period.

84. No-authorized generic agreements can take a variety of forms. Most commonly, they are structured as an "exclusive license," in which the brand company agrees to allow the first-filing generic exclusivity to market its generic product during the statutory 180-day exclusivity period.

85. In a report by the Federal Trade Commission issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, the FTC concluded that no-authorized generic agreements can provide significant value to a first-filer

generic company and have become a common form of payment from brands to generics to induce delayed generic entry. The FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition can reduce the first-filer generic's revenues by more than 50 percent during the 180-day exclusivity period.

86. For the first-filer generic, like Watson, of a branded product that sold hundreds of millions of dollars annually like Loestrin 24, the difference between selling the only generic product and competing against an authorized generic during the exclusivity period can amount to hundreds of millions if not billions of dollars. These economic realities are well known in the pharmaceutical industry. No-authorized generic agreements like the one between Warner Chilcott and Watson thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

4. Other generics often agree to the anticompetitive terms included in the agreement with the first filer.

87. 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 to 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 either elapsed or been forfeited.

88. Brand name manufacturers and first-filing generics can also game the system by structuring settlements in order to intentionally skirt 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

settling the litigation 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 a 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 over patents that the brand company did not assert against it in a Paragraph IV Litigation.

89. Second, third, or later filing generics can try to break the bottleneck, by bringing a declaratory judgment action that seeks to have a court declare that all Orange Book listed patents are either invalid or not infringed. This standard is high, but not insurmountable.

90. The anticompetitive agreement entered into between the brand and first filer often invited later ANDA filers to join the anti-competitive delayed entry date.

91. Later ANDA filers have relatively modest financial expectations. They are not the first filer, so have no 180 day exclusivity. They will enter into a situation where there is at least the brand and one other generic on the market (if not also a second, authorized generic). The drug has already been commoditized.

92. Without the anticompetitive agreement with the first filer, the later ANDA filers have pro-competitive incentives and conditions. They are motivated to fight patents, enter as early as possible, front money on challenging the brand's patent infringement suit (knowing that the first filer generic is also fighting a patent infringement suit), and even strike a deal with the brand to manufacture an authorized generic.

93. When an anticompetitive agreement with the first filer is already in place, litigation becomes less attractive to later filers. The later generics know that the first filer is not

leading the charge against the brand's patent infringement litigation (and has sometimes stipulated to the validity or enforceability of the patents as part of the settlement). The later generics have to bear the brunt of the litigation costs themselves. The standard for breaking the bottleneck is very high. And the possibility of doing an authorized generic deal is usually taken off the table by the terms of the settlement with the first filer.

94. Some later generics decide conspire with the brand company and first filer generics to solidify the bottleneck. They agree to drop their attacks on the brand's patents and to stay off the market for at least as long as the first filer generic promised to stay off the market. In exchange, the brand company pays them.

95. These abuses of the Hatch Waxman statutory scheme are fundamentally anticompetitive – they seek to extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead. The combination of these Hatch-Waxman abuses is deadly.

96. Here, Warner Chilcott's overarching scheme – which Watson and Lupin bought into and facilitated – resulted in years of unlawfully prolonged monopolization in the lucrative market for Loestrin 24 and its AB-rated generic equivalents. Warner Chilcott delayed generic entry by buying off Watson, the first ANDA filer. Buying off the first generic barred subsequent generics from entering the market until the first filer has entered and its exclusivity period had run (or unless another ANDA filer got a final judgment that every listed patent was invalid or not infringed). Warner Chilcott bought Lupin off as well, paying substantial consideration in exchange for its agreement to drop the patent challenges and delay entry until early 2014.

97. Warner Chilcott and the generic defendants exploited Hatch-Waxman to allocate the market for Loestrin 24 and its AB-rated generic equivalents. This case is not about the

protection patents they may provide to brand name drugs – this case is about the strategic manipulation of Hatch-Waxman in violation of antitrust law to prevent competition and permit competitors to share in the monopoly profits.

V. STATEMENT OF FACTS

A. The FDA approved the first Loestrin products in the 1970s.

98. 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 active ingredients in oral contraceptives since the early 1970s.

99. On April 30, 1973, the FDA simultaneously approved Warner Chilcott's NDAs for drugs later known as Loestrin Fe 1.5/30 (NDA 017875) and Loestrin Fe 1/20 (NDA 017876).⁷ Both were approved as a method of oral contraception in women. Both provide a continuous dosage regimen consisting of 21 progestogen-estrogen oral contraceptive tablets and seven ferrous fumarate tablets.

100. The contraceptive tablets contain the active ingredients norethindrone acetate and ethinyl estradiol. The ferrous fumarate tablets are non-hormonal, and – according to the label – are present only to facilitate ease of drug administration via a 28-day regimen and do not serve any therapeutic purpose. There is a question as to whether giving women iron pills helps combat the potential anemia sometime associated with menstruation.

101. The active tablets in Loestrin Fe 1.5/30 are pink and contain 1.5 mg norethindrone acetate and 30 mcg ethinyl estradiol. The active tablets in Loestrin Fe 1/20 are yellow and contain 1 mg norethindrone acetate and 20 mcg ethinyl estradiol.

⁷ For all Loestrin products, the "Fe" is sometimes dropped from the name. "Loestrin Fe 1/20" and "Loestrin 1/20" refer to the same product. "Loestrin 24 Fe" and "Loestrin 24" refer to the same product.

102. The numerator in the fractions in the Loestrin drug products' names refer to the number of milligrams of norethindrone acetate contained in an active pill. The denominator refers to the number of micrograms of ethinyl estradiol contained in an active pill.

103. On October 1, 1976, the FDA approved two additional Loestrin formulations, Loestrin 21 1.5/30 and Loestrin 21 1/20. The Loestrin 21 formulations include only active pills. The patient takes one tablet daily for 21 consecutive days followed by one week of no tablets. This is described as "three weeks on – one week off."

104. Loestrin 1/20 and Loestrin 21 1/20 both contain 21 of the same active pills. The only difference between a pack of Loestrin 1/20 and a pack of Loestrin 21 1/20 is that the Loestrin 21 1/20 pack does not contain any placebo/iron pills.

105. Loestrin 1.5/30 and Loestrin 21 1.5/30 both contain 21 of the same active pills. The only difference between a pack of Loestrin 1.5/30 and Loestrin 21 1.5/30 is that the Loestrin 21 1.5/30 does not contain any placebo/iron pills.

106. Generic versions of all four first generation Loestrin products have been available for decades. Defendant Watson and generic manufacturer Barr sell, or used to sell, FDA-approved generic version of all four products. Generic manufacturer Vintage Pharms LLC also sells, or used to sell, FDA-approved generic versions of Loestrin 1/20 and Loestrin 1.5/30 products.

107. This complaint addresses anticompetitive conduct among the defendants in the market for Loestrin 24 and its AB-rated generic equivalents. The regulatory history of Loestrin 24 is discussed in greater detail below. For now, it is helpful to know that Loestrin 24 contains the same active pills as Loestrin 1/20 and Loestrin 21 1/20, but includes 24 active pills in each pack (instead of the 21 active pills contained in each pack of Loestrin 1/20 and Loestrin 21 1/20).

B. Twenty years later, scientists at Eastern Virginia Medical School studied whether administering Loestrin 1/20 pills for 25 days (instead of 21 days) decreases the incidence of breakthrough bleeding.

108. Decades after the original Loestrin products were approved, scientists at the Eastern Virginia Medical School conducted studies in monkeys and women to determine whether administering Loestrin 1/20 pills for longer than the recommended 21 days decreased in the incidence of breakthrough bleeding.

109. Breakthrough bleeding, also referred to as spotting or intermenstrual bleeding, refers to vaginal bleeding that occurs midcycle, as opposed to during menstruation. Breakthrough bleeding is a common but annoying and potentially embarrassing side effect associated with many oral contraceptives. It is thought to occur more often when women begin taking an oral contraceptive or switch oral contraceptives.

110. Breakthrough bleeding generally is greatest in the first 3 to 4 months after starting an oral contraceptive, and it steadily declines and typically stabilizes by the end of the fourth cycle.

111. Breakthrough bleeding is different from withdrawal bleeding. The term “withdrawal bleeding” refers to bleeding that occurs in someone using oral contraceptives during the week that she is taking inactive/placebo pills. Unlike normal menstruation, it is not caused by the natural cycling of hormones that surrounds ovulation, causing the lining of the uterus to be built up (for implantation of a fertilized egg) and eventually shed; rather, it is caused by suddenly taking away an external source of estrogen, which causes the uterine lining to be sloughed off.

1. **A study of ten monkeys taking an adjusted, reformulated version of Loestrin 1/20 ostensibly showed less breakthrough bleeding with a 24-day oral contraceptive regimen than with a 21-day oral contraceptive regimen.**

112. Beginning in 1992, scientists at Eastern Virginia Medical School conducted a study of oral contraceptives in monkeys.

113. Ten adult female cynomolgus monkeys were divided into two groups. Five monkeys received an ultra low dose oral contraceptive for 21 consecutive days, followed by 7 non-treatment days. Five monkeys received an ultra low dose oral contraceptive for 24 consecutive days, followed by 4 non-treatment days. Each group was treated for 3 cycles.

114. The scientists, including Gary Hodgen, took commercially available Loestrin 1/20 tablets and ground them into a powder. They then “adjusted” the medication to fit the smaller body weight of the monkeys. Their “in house reformulation” resulted in a dose of 1.2 mcg/day ethinyl estradiol and 0.06 mcg norethindrone acetate.

115. According to the scientists, the monkeys that received their ultra low dose oral contraceptive regimen for 24 days manifest significantly less ($p < .05$) breakthrough bleeding in their second and third treatment cycles than females in the 21 day protocol. But this “trend” was not in evidence in the first treatment cycle ($p > .05$).

116. It would be expected that the incidences of breakthrough bleeding would decrease in later cycles.

117. Given the small number of monkeys in the study, the difference between a statistically significant results ($p < .05$) and a not statistically significant result ($p > .05$) may be as little as a single monkey. Meaning, that if a scientist had noticed breakthrough bleeding in a single additional monkey in the 21 day treatment group, or missed breakthrough bleeding in a

single monkey in the 25 day treatment group, the study may not have shown that the 25 day treatment group had significantly less breakthrough bleeding than the 21 day treatment group.

2. A study of thirty women showed no significant difference in breakthrough bleeding when taking Loestrin 1/20 active pills for 25 days instead of 21 days.

118. Beginning on or around January 1993, scientists at the Eastern Virginia Medical School – including Gary Hodgen – began a study where women took Loestrin 1/20 tablets for 25 consecutive days of the 28 day cycle.

119. The objective of the study was to suppress follicle stimulating hormone (FSH) levels during the first week of the menstrual cycle in order to, in part, minimize breakthrough bleeding.

120. In Hodgen's study, thirty healthy females (ages 22 to 35) were randomized to one of 2 low dose oral contraceptive regimens. All patients were non-smokers on no hormonal medications and had regular menstrual cycles without breakthrough bleeding. The 15 patients in Group A received a monthly regimen of 25 consecutive Loestrin 1/20 tablets followed by 7 placebo tablets. The 15 patients in Group B received a conventional regimen of 21 Loestrin 1/20 tablets followed by 7 placebo tablets. Each group was treated for 3 months.

121. The study participants knew they were taking Loestrin 1/20 tablets. Those in Group A knew they were taking Loestrin 1/20 tablets for 25 consecutive days of the 28 day cycle. Participants were not obligated to keep the study design or methods confidential.

122. Each subject self-reported bleeding patterns in a daily calendar.

123. The scientists compared the two groups with respect to bleeding patterns. The scientists did not find any significant differences in the amount of breakthrough bleeding between the 2 groups.

124. The study's results were described in an abstract submitted to the 43rd Annual Meeting of the Society for Gynecologic Investigation, held March 20-23, 1996, in Philadelphia, Pennsylvania. The authors were listed as L.M. Schenk, R.W. Whitcomb, G.D. Hodgen, and F.D. Anderson. The abstract disclosed that the study included 30 women participants who were taking Loestrin 1/20 active pills for 25 days straight. The abstract was later published in the Journal of the Society for Gynecologic Investigation on or around March 20, 1996.

125. In 1993, Loestrin 1/20 was commercially marketed by Parke Davis of Morris Plains, NJ (the marketing arm of Warner Lambert).

126. In 1993, Hodgen sent a letter proposing a "technology transfer agreement" with Parke Davis. Hodgen explained to Roger Boissonneault (the former Vice President of Female Health Care at Parke Davis and later the President of Warner Chilcott) why Hodgen believed that Parke Davis should pay Eastern Virginia Medical School for the "technology" used in the human subject study.

C. Hodgen applied for a patent for a 24-day regimen that decreases the incidence of breakthrough bleeding.

127. Despite the lack of differences in the incidence of breakthrough bleeding in Hodgen's human trial, Hodgen set out to obtain a patent for an oral contraceptive regimen with similar amounts of the same hormones contained in Loestrin 21 that decreased the incidence of breakthrough bleeding.

128. On July 22, 1994, Gary Hodgen applied for a patent for a method of female contraception *characterized by a reduced incidence of breakthrough bleeding* by administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the

daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate.⁸

129. The title of the patent is “Low Dose Oral Contraceptives *with Less Breakthrough Bleeding* and Sustained Efficacy” (emphasis added).

130. The patent specification states, “[i]t is the object of the present invention to provide a new estrogen-progestin combination and regimen for oral contraceptive use which maintains the efficacy and *provides enhanced control of endometrial bleeding*” (emphasis added).

131. Claim 1 recites

[a] method of female contraception *which is characterized by a reduced incidence of breakthrough bleeding* after the first cycle which comprises monophasically administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate. (Emphasis added.)

Claims 2-12 all depend on Claim 1.

132. In support of the claim that a 24-day regimen reduced breakthrough bleeding, Hodgen submitted data from the ten monkey study. The specification states “monkeys receiving their ultra low dose oral contraceptive regimen for 24 days manifest significantly less ($p < 0.05$) breakthrough bleeding in their second and third treatment cycle than females in the 21 day protocol.”

⁸ Hodgen appointed the law firm of Ostrolenk, Faber, Gerb, and Soffen of New York, NY to prosecute the application.

133. The specification did not refer to the study Hodgen did in women that showed no statistically significant differences in bleeding between women taking the active pills in Loestrin 21 for 25 days and women taking the active pills in Loestrin 21 for 21 days.

1. The preliminary amendment: Hodgen changed the amount of ethinyl estradiol reported in the summary of the invention.

134. In Hodgen's original patent specification, submitted on July 22, 1994, the summary of the invention referred to a method of female contraception that involved administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of the estrogen and progesterone are equivalent to about 5 – 20 *mcg* of ethinyl estradiol and about 0.025-10 mg of norethindrone acetate.

135. Hodgen's original Claim 1 referred to a method of female contraception in which the daily amounts of estrogen and progestin are equivalent to about 5 – 35 *mcg* of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate.

136. On October 7, 1994, before the Examiner had taken any action, Hodgen submitted a preliminary amendment changing the upper limit of the amount of ethinyl estradiol recited in the summary of the invention from 20 *mcg* – the amount contained in the active pills in Loestrin 21 – to 35 *mcg* – the upper bound recited in Claim 1.

2. The initial rejection: the Examiner concluded that the prior art taught low doses of ethinyl estradiol and 24 day dosing.

137. On January 19, 1995, the examiner rejected all 12 claims as obvious in light of prior art.

138. The examiner noted that a 1971 publication in Chemical Abstracts (a periodical index that provides summaries and indexes of disclosures in published scientific documents) by Craft et al. described a contraceptive regimen of 50 *mcg* ethinyl estradiol and 3 *mcg*

norethindrone acetate. Hodgen had not disclosed this reference in the list of relevant prior art he had previously submitted as part of his application.

139. The Examiner observed that Hodgen's claimed invention claimed a lower dose of ethinyl estradiol and a longer, 24 day, dosing regimen than the Craft reference, but that EPO 253,607 discloses contraceptive composition in which 15 mcg of ethinyl estradiol are administered with a progestin daily and a 24 day dosing regimen. The Examiner determined that administering a lower dose of ethinyl estradiol and to administer the ethinyl estradiol and norethindrone acetate combination for 24 of 28 days in a cycle was obvious in light of the Craft and the European reference.

3. Hodgen's amendment and response: Hodgen claimed the total estrogen (ethinyl estradiol) exposure is well below the total exposure in all other available combination contraceptives.

140. In response, Hodgen claimed that,

[T]he claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg EE (Craft uses 50mcg) and a regimen of 21 dosing days plus a 7-day pill free interval. With the claimed method, although there are more treatment days per year at say 20 mcg EE per day, the total drug exposure on a yearly basis remains significantly below the amount in an estrogen/progestin combination oral contraceptive which contains 30 or more mcg EE daily.

141. That is, Hodgen claimed (1) that all other commercially available combination oral contraceptive formulations contained at least 30 mcg ethinyl estradiol. This was not true. The active pills in Loestrin 1/20 and Loestrin 21 1/20 contained only 20 mcg ethinyl estradiol.

142. Hodgen knew that the commercially available active pills in Loestrin 1/20 and Loestrin 21 1/20 contained only 20 mcg of ethinyl estradiol. There were the very same active pills that he had used in the human study at EVMS back in 1993.

143. Hodgen also claimed (2) that the total amount of ethinyl estradiol exposure per year associated with his invention was less than the total amount of ethinyl estradiol exposure per year associated with any other estrogen/progestin combination oral contraceptive. This was not true. Both Loestrin 1/20 and Loestrin 21 1/20 contained 20 mcg ethinyl estradiol given for 21 days at a time. Hodgen invention claimed up to 35mcg of ethinyl estradiol given for 24 days at a time; Hodgen's "invention" delivers a greater amount of ethinyl estradiol per year than that delivered by Loestrin 1/20 or Loestrin 21 1/20. And even if Hodgen invention claimed only 20mcg of ethinyl estradiol per pill, Loestrin 1/20 and Loestrin 21 1/20 delivered less ethinyl estradiol per year because it delivered fewer doses.

4. The second rejection: The Examiner focused on the amount of ethinyl estradiol disclosed in prior art.

144. On November 22, 1995, the examiner again rejected all claims.

145. The examiner noted that Hodgen's remarks were "unpersuasive." She noted that Claims 1 recited a possible dosage of 35 mcg of ethinyl estradiol, which was only 15mcg lower than the 50 mcg dosage taught by Craft.

146. She further noted that Hodgen had not demonstrated that a dosage regimen different by only 15 mcg less of estrogen has unexpected contraceptive and reduced breakthrough bleeding results. Barring any unexpected results, Hodgen's purported invention was prima facie obvious and, therefore, unpatentable.

147. She noted, however, that claims 2-7 would be allowable if written as independent claims (as drafted, they depended on claim 1). Because, according to the examiner, the amount of estrogen administered in those claims was significantly less than the amount of estrogen administered in Craft.

5. Hodgen's amendment and response: Hodgen added a claim for 25 mcg of ethinyl estradiol

148. On January 24, 1996, the Examiner and Hodgen's patent attorney, Ed Meilman, discussed claims 1 and 8 during a telephone interview. Meilman highlighted the argument of his next response. He also asked the Examiner to add an additional claim drawn to 25 mcg of ethinyl estradiol. The Examiner agreed to enter the new claim.

149. On January 26, 1996, Hodgen again asked the examiner to add a new claim (as discussed during the telephone call two days earlier) for "The method of claim 1 in which the daily amount of estrogen is up to 25 mcg of ethinyl estradiol."

150. In response to the Examiner's second rejection, Hodgen argued that the claimed invention is not suggested by Craft when that reference is considered alone, and is directly contrary to the combined teachings of Craft and the Upton European patent reference, and thus is not obvious.

151. Hodgen argued that nothing in the Craft article teaches that the amount of ethinyl estradiol can be lowered below 50 mcg per dose.

152. Hodgen also argued that the European patent reference taught a combination of "low" dose estrogen and "very low" dose progestin, necessarily meaning that the amount of progestin must be lowered in a much greater amount. The combination was used there to treat menopause, not for contraceptive purposes. And the amount of progestin in Hodgen's claimed invention is not "very low," but to the contrary would be considered "very high" to one skilled in the art.

153. Hodgen's response did not disclose that there are commercially available, FDA approved products contain 20 mcg ethinyl estradiol per dose – namely Loestrin 1/20 and Loestrin 21 1/20.

6. The '394 Patent issues.

154. On February 5, 1996, the Examiner issued a notice of allowability for all claims.

155. After two supplemental amendments to ostensibly correct mathematical errors, Patent 5,552,394 issued in September 1996 (the '394 Patent).

156. Warner Chilcott is the fifth owner of the '394 Patent, which originally issued 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 acquired the '394 Patent from Pfizer in March 2003. In July 2004, Galen Holdings, PLC changed its name to Warner Chilcott.

157. Loestrin 24 is purportedly the commercial embodiment of the '394 Patent.

D. The '394 Patent would not have issued but for Hodgen's and his attorney's material misrepresentations and omissions to the PTO.

1. Hodgen never disclosed that study in humans showed no significant decrease in bleeding.

158. Hodgen sought to patent a method of female contraception characterized by a reduced incidence of breakthrough bleeding after the first cycle with comprises monophasically administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate.

159. Hodgen never disclosed to the Examiner that he had personally conducted a study where 15 women were monophasically administered a combination of estrogen and progestin for 24 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to 20 mcg of ethinyl estradiol and about 1 mg of norethindrone acetate that found no reduction in the incidence of breakthrough bleeding (as compared to a group of 15 women taking the same pills for only 21 days).

160. The human study is a public use of Hodgen's "invention" more than one year before Hodgen applied for the '394 Patent (July 22, 1994) and invalidates that patent. This public use invalidates the patent regardless of whether the study showed a difference in the incidence of breakthrough bleeding.

161. The human study is also a data point that directly contradicts Hodgen's claim, as embodied in the '394 Patent, that the method of contraception described in the patent specification and Claim 1 reduced the incidence of breakthrough bleeding after the first cycle. Hodgen had an obligation to disclose this information to the PTO.

162. Hodgen and his colleagues began the human study in or around January 1993. He reported the results in an abstract on or around March 20, 1996 -- almost six months before the '394 Patent issued. Hodgen almost certainly knew the results of the study well before he submitted the abstract.

163. Hodgen submitted additional correspondence to the PTO after the abstract was released, including a May 3, 1996 amendment to correct a mathematical error. Hodgen could have brought the unfavorable study results to the Examiner's attention in that submission or in a separate submission. He chose not to.

164. Instead, the only data Hodgen presented to the Examiner to support his claim that the method of female contraception described in his patent specification and claims -- administering a combination of 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate for 23-25 days -- is characterized by a reduced incidence of breakthrough bleeding was the monkey study. Which was not a study in women, only included 5 monkeys in each group, relied on scientists subjective assessments of whether monkeys had experienced breakthrough bleeding, did not administer pills with the amounts of ethinyl estradiol or

norethindrone acetate covered by Claim 1, and may have only shown statistical significance because of the extremely small sample size and the removal of one monkey from the study.

165. Hodgen intended to deceive the PTO by not disclosing information known to him that contradicted the '394 patent specification (which address an oral contraceptive regimen that provides enhanced control of endometrial bleeding) and claims (which claim a method of female contraception which is characterized by a reduced incidence of breakthrough bleeding after the first cycle).

166. Had Hodgen disclosed the existence of the human study, the Examiner would not have issued the patent. Either for public use or because it undercut the only data Hodgen had submitted in support of his contention that the method of contraception he described reduced the incidence of breakthrough bleeding after the first cycle.

2. Hodgen misrepresented the amount of ethinyl estradiol and norethindrone acetate in commercially available combination oral contraceptives.

a. Hodgen misrepresented that no commercially available oral contraceptives contained less than 30 mcg of ethinyl estradiol.

167. The originally-filed patent application claimed a method of using an oral contraceptive containing 5-35 mcg of ethinyl estradiol and .025 to 10 mg of norethindrone acetate for 23-25 consecutive days.

168. The examiner initially rejected all claims as obvious in light of earlier disclosures. European Patent No. 253,607 ("Upton") discloses a method of using an oral contraceptive or at least 23 days. And an article, Craft, I.L., T.J. Peters, "Quantitative changes in plasma amino acids induced by oral contraceptives," Clin. Sc. (1971), 41(4), 301-07 ("Craft"), discloses an oral contraceptive combining 50 mcg of ethinyl estradiol and 3 mg of norethindrone acetate.

169. On January 23, 1995, the applicants told the PTO that all commercially available oral contraceptive combination formulations “contain at least 30 mcg of EE.”

170. On July 19, 1995, the applicants told the PTO,

[T]he claimed regimen leaves the patients with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. *Those all contain at least 30mcg EE (Craft uses 50mcg)* and a regimen of 21 dosing days plus a 7-day pill free interval.

171. This statement was materially false.

172. As Hodgen was well aware, Loestrin 1/20 and Loestrin 21 1/20 – both of which had been available since the 1970’s – contained 20 mcg of ethinyl estradiol. Hodgen knew this from his experience with the human study and the monkey study.

173. Hodgen and others began the monkey study in 1992. The investigators gave Loestrin 1/20 tablets, adjusted for the smaller body weight of the primates. According to an internal report, Hodgen stated that the “in-house reformulation was achieved by grinding to powder a commercially available monophasic pill (Loestrin 1/20, Parke Davis, Morris, NJ) which originally contained 1 mg of norethindrone acetate and 20 mcg of ethinyl estradiol per tablet in a conventional 21 day pack, along with 7 iron containing placebos.”

174. Because Hodgen actually used Loestrin 1/20 tablets in this study, he knew first-hand about Loestrin 1/20 tablets, including the amount of ethinyl estradiol they contained, as early as 1992.

175. Hodgen also knew that the 1993 EVMS clinical study in women used “commercial blister packs” of Loestrin 1/20.

176. Hodgen also knew that oral contraceptives approved outside of the United States contained less than 30 mcg ethinyl estradiol.

177. Hodgen intended to deceive the PTO by misrepresenting that no other commercially available oral contraceptive contained less than 30 mcg of ethinyl estradiol.

178. The Examiner relied on Hodgen's representation that no other commercially available product contained less than 30 mcg of ethinyl estradiol to overcome the Examiner's original obviousness rejection. Had Hodgen disclosed that Loestrin 1/20 included active tablets with less than 30 mcg of ethinyl estradiol, the Examiner would not have withdrawn her rejection and the PTO would not have issued the patent.

b. Hodgen misrepresented that his claimed regime exposed women to less estrogen than existing oral contraceptives.

179. Hodgen also claimed that the total amount of ethinyl estradiol exposure per year associated with his invention was less than the total amount of ethinyl estradiol exposure per year associated with any other estrogen/progestin combination oral contraceptive. This was not true.

180. Both Loestrin 1/20 and Loestrin 21 1/20 contained 20 mcg ethinyl estradiol given for 21 days at a time. The annual exposure to estrogen from the Loestrin 1/20 or Loestrin 21 1/20 regimen taken for 21 days of a 28 day cycle is just over 5.5mg.

181. The dosing regimen claimed in the '394 patent application included up to 35 mc of ethinyl estradiol for up to 25 consecutive days of the 28 day cycle. Over a period of one year, women following the claimed regimen could be exposed to more than 11.4 mg of estrogen.

182. The claimed regimen delivers a greater amount of ethinyl estradiol per year than that delivered by Loestrin 1/20 or Loestrin 21 1/20. And even if Hodgen's invention claimed only 20mcg of ethinyl estradiol per pill, Loestrin 1/20 and Loestrin 21 1/20 deliver less ethinyl estradiol per year because they deliver fewer doses.

183. Because Hodgen actually used Loestrin 1/20 tablets in this study, he knew firsthand about Loestrin 1/20 tablets, including the amount of ethinyl estradiol they contained, as early as 1992. He also knew that the labeling for Loestrin 1/20 instructed women to take the 21 active tablets contained in the blister pack for 21 days each cycle.

184. The Examiner relied on Hodgen's representation that no other commercially available product exposed women to less estrogen. Had Hodgen disclosed that Loestrin 1/20 exposed women to less ethinyl estradiol per year than his purported invention, the PTO would not have issued the patent.

c. Hodgen failed to disclose prior art that taught taking oral contraceptives for more than 21 days.

185. Hodgen intentionally concealed a prior art publication that taught one skilled in the art to increase a 21 day schedule of commercial oral contraceptives to 23 days.

186. A 1985 article entitled "Missed pill conception: fact or fiction" observed the likelihood of conception by a woman using oral contraceptives who misses a pill can be diminished by reducing the pill-free interval for a 28 day cycle. Molloy et al., *Br. Med. J.* 1985; 290: 1474-5 ("Molloy").

187. In Molloy, the authors state: "To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack and would still permit a withdrawal bleed without the risk of significant follicular development."

188. Molloy teaches increasing a 21 day schedule of commercial oral contraceptives to 23 days.

189. Molloy is material to the patentability of the claims of the '394 Patent because the claims of the patent extend the 21 day schedule to 23-25 days.

190. Hodgen was aware of the Molloy reference, as shown by a letter Hodgen sent Warner-Lambert during December 1990.

191. Hodgen never disclosed Molloy to the PTO during the prosecution of the '394 Patent claims.

192. Hodgen intended to deceive the PTO by withholding Molloy from consideration during the examination of the '394 Patent claims.

193. If the examiner had known that an article published in a British Medical Journal almost a decade earlier had disclosed taking active pills for longer than 21 days, followed by fewer than the typical 7 inactive pills, he would not have approved the '394 patent. The reference supports the obviousness of the invention and undermines the inventor's claim that this administering active pills for 23-25 days (followed by fewer than 7 inactive tablets) was novel.

E. In 2006, the FDA concludes that Loestrin 24 did not reduce the incidence of breakthrough bleeding.

194. On April 15, 2005, Warner Chilcott submitted an NDA for approval to market a new drug that later became known as Loestrin 24 Fe. This complaint uses the terms "Loestrin 24 Fe" and "Loestrin 24" interchangeably.

195. Loestrin 24 is, purportedly, a commercial embodiment of the '394 Patent.

196. Loestrin 24 provides a dosage regimen consisting of 24 white progestogen-estrogen contraceptive tablets and 4 brown ferrous fumarate placebo tablets. The active tablets contain 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. The placebo tablets contain ferrous fumarate and do not serve any therapeutic purpose. The patient takes one tablet daily for 24 consecutive days followed by four days of no tablets.

197. Loestrin 24 contains the same active tablets (and the same daily doses of norethindrone acetate and ethinyl estradiol) as Loestrin 1/20 and Loestrin 21 1/20. Loestrin 24 is

taken for 24 consecutive days instead of 21 consecutive days – *i.e.* an additional 3 days during each 28-day treatment cycle.

198. The FDA observed that Loestrin 24 exposes women to daily doses of ethinyl estradiol and norethindrone acetate that are identical to those of Loestrin 1/20 and cumulative monthly doses that are intermediate between those of the 2 approved products.

199. Warner Chilcott (then Galen Holdings PLC) began discussing the design for the investigational new drug study for a 24 days version of Loestrin with the FDA as far back as September 2003.

200. In designing the phase 3 clinical trials presented in the NDA, Warner Chilcott and the FDA presumed that Loestrin 24 would be at least as effective as Loestrin 1/20 in preventing pregnancy and that, because each tablet of Loestrin 24 contains less active hormones than Loestrin 1.5/30 and the cumulative monthly dose of each steroid would be less than that of Loestrin 1.5/30, Loestrin 24 would be at least as safe as the approved product.

201. Warner Chilcott hypothesized that extending the duration of active treatment from 21 days to 24 days, thereby decreasing the drug-free interval to 4 days, might decrease the frequency of breakthrough spotting/bleeding associated with the use of low estrogen dosage combination oral contraceptives. Warner Chilcott speculated that such a reduction in breakthrough spotting/bleeding might lead to better long-term compliance with dosing and perhaps fewer unplanned pregnancies.

202. Warner Chilcott's investigational new drug study included two treatment groups, one taking Loestrin 24 and one taking Loestrin 1/20. Each group took the same active pills; one group took the contraceptive pills for 24 days and the other group took the contraceptive pills for 21 days.

203. The studies' treatment groups were very similar to the treatment groups in Hodgen's EVMS human study, done in the early 1990's. Both studies included a Loestrin 1/20 treatment group. Hodgen's study included a group of women taking Loestrin 1/20 active pills for 25 days. Warner Chilcott's IND study included a group of women taking Loestrin 1/20 active pills for 24 days.

204. Seven hundred forty three (743) women started treatment with Loestrin 24. Five hundred eighty (580) completed at least 161 days of treatment (about 6 cycles).

205. The FDA reviewed the data from the Loestrin 24 IND study and concluded that, "for the most part, there were not statistically significant or clinically meaningful differences across the 2 treatment groups in term of any parameters of bleeding that were examined." The FDA noted that "the findings of Study PR-0393 do not support the Applicant's hypothesis that 3 additional days of active treatment (i.e., extending the active treatment period from 21 days to 24 days during each 28-day cycle) would reduce the incidence of intracyclic bleeding."

206. The FDA noted that even though the data had not shown that Loestrin 24 had a lower incidence of breakthrough bleeding than Loestrin 1/20, the drug should nonetheless be eligible for approval if it was both safe and effective for the prevention of pregnancy.

207. On February 17, 2006, the FDA approved Loestrin 24 as a method of contraception in women.

208. The FDA warned Warner Chilcott that it could not conclude that Loestrin 24 was superior to Loestrin 1/20, and that the label could not include any comparative claims.

209. Despite the FDA's conclusion that Loestrin 24 did not reduce the incidence of breakthrough bleeding, Warner Chilcott markets Loestrin 24 as providing an effective low dose birth control with shorter, lighter periods that produce less bleeding.

210. Warner Chilcott's has earned over \$1.75 billion in revenue from Loestrin 24 sales to date.

Year	Annual Revenue
2012	\$389 million
2011	\$396 million
2010	\$342 million
2009	\$247 million
2008	\$197 million
2007	\$148 million
2006	\$ 44 million

F. Warner Chilcott lists the '394 Patent in the Orange Book.

211. Despite the FDA's conclusion that the IND showed no significant difference either in the incidence of intracyclic bleeding or in the number of intracyclic bleeding/spotting days across the Loestrin 1/20 and Loestrin 24 treatment groups, and the fact that the '394 Patent covered an oral contraceptive regimen characterized by a reduced incidence of breakthrough bleeding after the first cycle (based on data that ostensible compared bleeding rates in monkeys taking the active pills in Loestrin 1/20 for 21 and 24 days), Warner Chilcott listed the '394 Patent in the FDA Orange Book as covering Loestrin 24 or a method of using Loestrin 24.

212. On April 15, 2005, Warner Chilcott identified the '394 Patent, and only the '394 Patent, as covering Loestrin 24. Warner Chilcott told the FDA that the '394 Patent expired on July 22, 2014.

213. Because the '394 Patent claims only a narrow method of using active ingredients that have been employed for decades as oral contraceptives, generic manufacturers were eager to apply for FDA approval to market generic versions of Loestrin 24 long before the expiration of the '394 Patent. The '394 Patent was inapplicable, invalid, and unenforceable.

1. The '394 Patent does not cover Loestrin 24.

214. The '394 Patent claims a method of female contraception which is characterized by a reduced incidence of breakthrough bleeding after the first cycle. That method is comprised of administering a specific combination of hormones for 24 days.

215. According to the FDA, the data Warner Chilcott presented in its NDA did not support its hypothesis that Loestrin 24 reduced breakthrough bleeding. The FDA determined, after comparing the incidence of bleeding in the group taking Loestrin 24 and the group taking Loestrin Fe 1/20, that there was no statistically or clinically significant difference in bleeding between the two groups. The FDA concluded that Warner Chilcott had not provided data to show that Loestrin 24 reduced the incidence of breakthrough bleeding as compared to Loestrin 1/20.

2. The '394 Patent is obvious in light of the prior art.

216. Loestrin Fe 1/20 contains the specific estrogen and progestin compounds recited in the claims of the '394 Patent, in the claimed amounts and in the claimed weight ratios. But the active pills in Loestrin Fe 1/20 are taken for 21 days, not the 23-25 days contemplated by the '394 Patent.

217. Based on the prior art, it was obvious to administer active pills for more than 21 days.

218. The prior art teaches that a seven day pill-free period leads to follicular development, which can lead to pregnancy. The prior art proposes to provide improved suppression of follicular development by using a 24-day regime of active pills in oral contraceptive products while incrementally increasing the progestogen.

219. The prior art teaches that a seven-day pill-free interval may be associated not only with diminished contraceptive efficacy, but also symptoms of estrogen withdrawal such as migraine headaches.

220. The prior art teaches that a 7-day pill-free interval may be associated not only with diminished contraceptive efficacy, but also symptoms of estrogen withdrawal such as migraine headaches.

221. The prior art teaches that the incidence of intermenstrual bleeding might be reduced by giving an additional combination tablet in each cycle.

222. There are examples in the prior art of other 24-day regimes that are safe and effective. One of ordinary skill would thus have expected that administering a combination of estrogen and progestin for 23-25 days, or specifically for 24 days, would be safe and effective.

223. The prior art suggests that the seven-day pill-free interval could be shortened to achieve additional benefits, such as reduced risk of follicular development, improved contraceptive efficacy, reduced breakthrough bleeding, as well as relief from certain symptoms of estrogen withdrawal such as migraine headaches. One skilled in the art would be motivated to reduce the number of pill-free days by administering additional active pills.

3. The '394 Patent is invalid and/or unenforceable due to Hodgen's misrepresentations to the PTO.

224. As described above, Hodgen made multiple material misrepresentations to the PTO during the prosecution of the '394 Patent application. In the absence of some or all of those misrepresentations and omissions, the '394 Patent would not have issued.

225. If the '394 Patent hadn't issued, it could not have been listed in the Orange Book or asserted against generic competitors in patent infringement actions. No patents would have prevented generic competitors from bringing an AB-rated form of Loestrin 24 to market.

226. Put differently, but for Hodgen's fraud on the PTO there would have been no pretextual patent infringement lawsuit, and no guise for Warner Chilcott to pay Watson to stay off the market for five years in a nominal settlement agreement.

G. Warner Chilcott enters into reverse payment settlement agreements with Watson and Lupin.

1. Warner Chilcott Sues Watson for infringing the '394 patent.

227. On or about April 17, 2006, defendant Watson notified Warner Chilcott that Watson had filed ANDA No. 78-267 in order 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.

228. On July 28, 2006, Warner Chilcott sued Watson in the United States District Court for the District of New Jersey, alleging that Watson's generic Loestrin 24 product would infringe the '394 Patent. Simply by filing the case, Warner Chilcott prevented Watson from obtaining FDA approval to market generic Loestrin 24 for at least two-and-a-half years. 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.

229. During the litigation, Watson challenged the validity and enforceability of the '394 Patent, as well as Warner Chilcott's infringement allegations. Watson raised many of the arguments about invalidity, unenforceability, and non-infringement discussed above. Watson filed an amended answer and counterclaim setting out the basis for its allegations of invalidity, unenforceability, and non-infringement on January 23, 2008.

230. To prevent generic entry by relying on the '394 Patent, Warner Chilcott would have had to defeat each of Watson's bases regarding invalidity and unenforceability and prove that Watson infringed the '394 Patent. Warner Chilcott would have inevitably lost the infringement suit. Instead, Warner Chilcott decided to protect its monopoly by unlawfully paying Watson to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24.

231. From the inception of the case, Watson fought tooth and nail to obtain discovery materials and consistently opposed Warner Chilcott's efforts to stall discovery. Then, beginning in May 2008, the parties entered into a series of stipulations to extend the close of discovery.

232. On January 15, 2009, Warner Chilcott and Watson filed a stipulation of dismissal. The parties settled before the parties briefed, and before the Court finally decided, the substantive issues of invalidity, unenforceability, and infringement.

2. Warner Chilcott and Watson Enter an Exclusion Payment Agreement

233. Having obtained the goal of the patent infringement case against Watson – staying FDA approval of Watson's generic Loestrin 24 application for nearly 30 months – Warner Chilcott decided to terminate the case. On or about January 12, 2009 – 29 months after Warner Chilcott had filed the case – Warner Chilcott and Watson entered into an agreement to delay entry of generic Loestrin 24 ("Watson 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 adjudicating the patent case had not issued any substantive rulings regarding the merits of the case.

234. Under the Watson Exclusion Payment Agreement, Watson covenanted and agreed not to sell 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; (3) the date on which another generic version of Loestrin 24 entered the market; or (4) the date on which any third party obtained a final and non-appealable judicial order that the '394 Patent is invalid, unenforceable or not infringed by that third party's generic version of Loestrin 24.

235. In return for Watson's agreement to drop its challenge to the '394 Patent and to delay entry of its generic Loestrin 24 product, Warner Chilcott agreed to pay Watson substantial sums. Warner Chilcott's payments to Watson under the Agreement took at least five forms.

236. First, under the Agreement, Warner Chilcott covenanted and agreed not to market, supply or license an authorized generic version of Loestrin 24 during Watson's first 180 days of marketing. Under the Agreement, Warner Chilcott and its affiliates expressly agreed not to market or supply, and expressly agreed not to grant 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. Indeed, Warner Chilcott has marketed authorized generic versions of several of its other branded drugs, including its oral contraceptive, Dovonex. Obtaining relief from authorized generic competition was a huge financial benefit to Watson.

237. Second, Warner Chilcott agreed to grant to Watson a “non-exclusive, fully paid, worldwide, royalty-free irrevocable license, under the [’394 Patent] and all regulatory exclusivities pertaining thereto” to market Loestrin 24 everywhere in the world beginning January 22, 2014. The license to market Loestrin 24 both inside and outside the United States has substantially more value to Watson than a license to market the product only in the United States.

238. Third, the Agreement provided that Warner Chilcott would 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.

239. Fourth, the Agreement gave 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.

240. Fifth, Warner Chilcott covenanted and agreed not to grant a license to any other manufacturer to produce a generic version of Loestrin 24 – whether under Warner Chilcott’s NDA or under any ANDA – 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 had likely forfeited its entitlement to 180-day exclusivity under the Hatch-Waxman Act because it had failed to obtain tentative FDA approval to market generic Loestrin 24 within 30 months of submitting its ANDA in April 2006.

Thus, the contractual exclusivity granted by Warner Chilcott had substantial value to Watson and precluded generic competition at the expense of Plaintiff and other Class Members.

241. If for some reason, Watson did not forfeit its 180-day exclusivity, then its agreement with Warner Chilcott created a bottleneck that prevented FDA from approving any subsequent ANDA until 180 days after January 22, 2014. Either way, defendants win at the expense of plaintiff and the Class – either Watson obtained additional payment in the form of guaranteed six-month exclusivity or Watson agreed to delay its launch of generic Loestrin 24 in exchange for (other) payments, thereby creating an approval bottleneck that prevents other generics from entering the market until six months after Watson.

242. The Warner Chilcott/Watson agreement also invited later generics to agree with the anti-competitive delayed entry date. The agreement affixed a late entry day of January 22, 2014, retained the 180-day bottleneck, and included escape clauses that permitted Watson to come to market if another generic broke the bottleneck and/or launched at risk.

243. The agreement provided:

If a Third Party commercially launches a generic version of [Loestrin 24] without authorization from [Warner Chilcott], the [Warner Chilcott] shall grant to Watson the license granted pursuant to Paragraph 6 hereof, effective on the same date as such Third Party launch.

Warner Chilcott and Watson agreed that if another generic came to market before January 22, 2014, then Watson's product could come to market immediately. The agreement also permitted Watson launch immediately launch if a court entered a final, nonappealable judicial order that the '394 patent is invalid, unenforceable, or not infringed. But, in the event that Warner Chilcott successfully caused that generic to stop selling its product, Watson would have to, likewise, stop selling its generic product until another generic came to market.

244. These escape clause provisions also created incentives for Warner Chilcott to (1) prevent a decision on the validity and enforceability of the '394 patent and (2) similarly buy off all later generics in order, in order to prevent Watson from simultaneously launching its generic. The agreement contemplates that Warner Chilcott may "succeed" in having other generics "cease" sales through means other than obtaining a court injunction.

245. Warner Chilcott made these payments in exchange for Watson's agreement to delay generic competition to Loestrin 24 for *five years*. Absent Watson's agreement to delay entry of generic Loestrin 24, Warner Chilcott would not have agreed to: (a) refrain from launching, or granting a license to others to launch, an authorized generic Loestrin 24 during Watson's first 180 days of marketing; (b) grant Watson a license to market Loestrin 24 globally beginning January 22, 2014; (c) designate Watson as a co-promoter of Femring; (d) grant Watson an exclusive license to market and sell Generess Fe; (e) guarantee Watson 180 days of exclusivity, which it had otherwise forfeited, to market a generic version of Loestrin 24; and/or (f) grant the price and/or other terms that it did under those provisions of the Agreement. Warner Chilcott paid Watson to keep its AB-rated generic version of Loestrin 24 off the market for five years.

246. January 22, 2014 is the expiration date of the '394 Patent. Watson agreed to stay off the market until January 22, 2014. The settlement did not include a negotiated early entry date.

3. Warner Chilcott Sues Lupin for Infringing the '394 Patent.

247. 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.

248. On or about July 2009, six months after the announcement of the agreement between Warner Chilcott and Watson, Lupin notified Warner Chilcott that it had filed ANDA No. 091398 for the purpose of marketing 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.

249. 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.

250. 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 sole purpose in filing the case was to obtain the 30-month hiatus from generic competition, regardless of whether it ultimately won the case. Indeed, had the case proceeded to a litigated conclusion, Warner Chilcott was very likely to have lost.

251. 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.

252. To prevent generic entry by enforcing the '394 Patent, 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

monopoly by paying Lupin to withdraw its challenges to the validity and enforceability of the '394 Patent and delay its introduction of generic Loestrin 24.

4. Warner Chilcott and Lupin Enter an Exclusion Payment Agreement.

253. Had Lupin obtained a final judgment invalidating the '394 Patent, it would have broken the bottleneck caused by the Watson Exclusion Payment Agreement. Instead, to extent and maintain its monopoly, Warner Chilcott made sure that Lupin, the second ANDA-filer for Loestrin 24, did not litigate the case conclusion. Before the court reached a determination on the issue of invalidity and/or non-infringement of the '394 Patent, Warner Chilcott paid Lupin to drop its patent challenge and stay out of the market until after Watson was permitted to enter the market pursuant to the Watson Exclusion Payment Agreement.

254. 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 ("Lupin Exclusion Payment Agreement") and dismissed the case. Pursuant to that Agreement, Lupin agreed to drop its challenge to the '394 Patent and to delay entry of its generic version of Loestrin 24 until July 22, 2014, the month that the '394 Patent expires. In exchange, Warner Chilcott agreed to pay Lupin substantial sums. Warner Chilcott's payments to Lupin under the Lupin Exclusion Payment Agreement took at least two forms.

255. First, the Lupin Exclusion Payment 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 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 in October 2011, and since that time has made substantial sales of that product. But for the Lupin Exclusion Payment Agreement, Lupin could not have begun making generic Femcon Fe sales until the end of the 30-month stay in February 2012.

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

257. 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 other agreements). 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.

258. Lupin dropped its patent challenges and accepted the launch date Warner Chilcott and Watson agreed to in the earlier Warner Chilcott / Watson agreement – September 22, 2014. In doing so, it joined in Warner Chilcott and Watson's ongoing conspiracy to allocate the relevant market. It also ensured that its own earlier launch would not trigger Watson's launch (as permitted by the terms of the Warner Chilcott / Watson agreement).

259. Warner Chilcott and Lupin continue to adhere to the Lupin Exclusion Payment Agreement.

260. As described more fully below, Warner Chilcott has delayed generic entry in order to both extend and protect its Loestrin 24 monopoly and to buy time to switch prescriptions to a follow-on branded version of Loestrin before generic Loestrin 24 became available.

H. Warner Chilcott's Agreements with Watson and Lupin required continuing performance.

261. The anticompetitive effects of the reverse payment settlement agreements stem not solely from the execution of the agreements but also from the continued performance of those agreements over the past four years. For the defendants' anticompetitive scheme to be effective, they must each actually take steps to abide by the agreements. That ongoing performance includes, but is not limited to the following:

262. According to the terms of the agreements, Warner Chilcott must actually pay Watson and Lupin according to the terms of the agreements.

263. According to the terms of the agreements, Warner Chilcott must prosecute and delay later ANDA filer's attempts to break the bottleneck.

264. According to the terms of the agreements, Watson and Lupin must each actually stay off the market through January 22, 2014.

265. According to the terms of the agreements, Warner Chilcott has to cut deals to pay off other, later generic filers (including Lupin) to protect the entry date Watson agreed to.

266. According to the terms of the agreements, Warner Chilcott, Watson, and Lupin must prevent a court ruling on the merits of the '394 Patent.

267. According to the terms of the agreements, Warner Chilcott must continue to overcharge direct purchasers for *years*, continuing up to and through the present.

I. In the absence of generic competition, Warner Chilcott began marketing Lo Loestrin.

268. In order to exploit the market “disconnect” and maintain its monopoly and supracompetitive sales in the Loestrin market, it was necessary for Warner Chilcott to defeat the successful entry of generic Loestrin. In response to the competitive threat from generic Loestrin, Warner Chilcott devised a so-called “life cycle management” plan which involved (among other things) the rote filing of patent infringement cases regardless of their merit and unlawful pay-offs to generic manufacturers to delay entry. As part of the life cycle management plan, Warner Chilcott took an additional step to extend its monopoly: it made modifications to the Loestrin and gave it a new name – Lo Loestrin. The hopping of this product from Loestrin 24 to Lo Loestrin Fe afforded no therapeutic or economic benefit other than to further delay generic competition and prevent price reductions for Warner Chilcott’s Loestrin franchise.

269. Using the 30-month stays obtained by filing meritless patent lawsuits, as well as the additional time obtained by paying off generic manufacturers to delay entry, Warner Chilcott modified the chemical composition of its Loestrin product so that generic versions of Loestrin could not be substitutable for branded Loestrin when they finally entered the market. Warner Chilcott designed this product hop in order to protect Loestrin sales from generic competition.

270. On March 26, 2009, Warner Chilcott submitted an application to the FDA for approval to market a revised version of Loestrin, which ultimately became known as Lo Loestrin Fe. Lo Loestrin was not superior to Loestrin 24, but its development and launch impaired generic competition. Warner Chilcott timed the development and marketing of Lo Loestrin to impose the greatest possible harm to generic competition.

271. Lo Loestrin offered no new benefits to consumers as compared to Loestrin 24. Both versions of the product contain the same active ingredients. In fact, there were significant

disadvantages to taking Lo Loestrin instead of Loestrin 24: the clinical studies for Lo Loestrin revealed that the pregnancy rate (Pearl Index) for women using Lo Loestrin was more than 60% higher than the rate for Loestrin 24. Additionally, the introduction of Lo Loestrin was potentially harmful to patients who had previously been taking Loestrin 24, due to the well-documented difficulties and dangers inherent in transferring patients from one oral contraceptive to another.

272. Indeed, but for the effect of impairing generic competition, Warner Chilcott expected that launching Lo Loestrin would cause the company to lose sales and revenues, increase costs, and decrease efficiency.

273. It was essential to Warner Chilcott that it launch and convert as many potential Loestrin 24 prescriptions as possible to Lo Loestrin before generic versions of Loestrin 24 were available in the market. It is well established in the pharmaceutical industry that that unless a brand manufacturer launches its follow-on product before entry of a generic version of the original product, it is unlikely to launch at all. 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 (5 July 2009), available at http://www.european-council.europa.eu/media/16600/nldoc/j7_amsx3/pharmaceutical_sector_inquiry_final?start=006-00c=10.

274. La Loestrin offers no medical, convenience, or other benefits to consumers, as compared to Loestrin 24, and no legitimate economic benefits to Warner Chilcott.

Consequently, Warner Chilcott's ploy of switching prescriptions to Lo Loestrin depended on launching Lo Loestrin before generic versions of Loestrin 24 were available. Beating the generics onto the market would allow Warner Chilcott to effectuate the shift to Lo Loestrin at a time when no competing manufacturer had the incentive or ability to counter Warner Chilcott's marketing message to doctors.

275. Absent Warner Chilcott's unlawful payments to Watson and Lupin to delay entry, generic Loestrin 24 would have been available long before the FDA approved Lo Loestrin for sale. Thus, in the absence of Warner Chilcott's unlawful payments to Watson and Lupin, Warner Chilcott would not have launched Lo Loestrin or, if it had, it would have made few sales.

276. 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.

VI. ANTICOMPETITIVE EFFECTS

277. 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.

278. Warner Chilcott's overarching anticompetitive scheme, and the Generic Defendants' participation in it, has 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.

279. The defendants' unlawful conduct under this scheme is ongoing, and it continues to cause injury to the plaintiff and the member of the Class.

280. Defendants' scheme and unlawful payments harmed plaintiff and the Class by depriving them of: (1) a market in which manufacturers and distributors of generic drugs make 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: (a) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24; and (c) allocate 100% of the U.S. market for an oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20mcg) tablets and 4 ferrous fumarate tablets to Warner Chilcott.

281. But for the anticompetitive scheme: (i) 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; (ii) 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 (iii) Warner Chilcott would not have developed or marketed Lo Loestrin and switched a substantial portion of sales to that product and/or generic Loestrin 24 would have entered the market before Lo Loestrin, thereby impeding Warner Chilcott from switching prescriptions to Lo Loestrin.

282. 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 already entered the market with an authorized generic version of Loestrin 24.

283. As a consequence, plaintiff 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.

VII. EFFECT ON INTERSTATE COMMERCE

284. At all material times, Loestrin, manufactured and sold by Warner Chilcott, was shipped across state lines and sold to customers located outside its state of manufacture.

285. During the relevant time period, in connection with the purchase and sale of Loestrin, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

286. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of defendants were within the flow of, and have substantially affected, interstate commerce.

VIII. CLASS ALLEGATIONS

287. American Sales, on behalf of itself and all class members, seek damages, measured as overcharges, trebled, against defendants based on allegations of anticompetitive conduct in the market for Loestrin 24 and its AB-rated generic equivalents – *i.e.*, oral

contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo).

288. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as representative of a Class defined as follows:

All persons or entities in the United States and its territories who purchased Loestrin 24 directly from Warner Chilcott at any time during the period May 14, 2009 through and until the anticompetitive effects of the defendants' conduct cease (the "Class Period").

Excluded from the class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal or state governmental entities.

289. Members of the class are so numerous that joinder is impracticable. American Sales believes that there are dozens of class members. Further, the class is readily identifiable from information and records that are required by law to be maintained by the defendants.

290. Plaintiff's claims are typical of the claims of the members of the class. American Sales and all members of the Class were damaged by the same wrongful conduct of the defendants. Specifically, they paid artificially inflated prices for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo) and were deprived – and are still deprived – of the benefits of competition from cheaper generic versions of Loestrin 24 as a result of the defendants' wrongful conduct.

291. American Sales will fairly and adequately protect and represent the interests of the class. American Sales's interests are coincident with, and not antagonistic to, those of the class.

292. American Sales and the class are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

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

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

- a. whether Warner Chilcott willfully obtained and/or maintained monopoly power over Loestrin 24 and its generic equivalents;
- b. whether Warner Chilcott entered into a contract, combination, and/or conspiracy with the generic defendants to restrain trade;
- c. whether Defendants unlawfully excluded competitors and/or potential competitors from the market for oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo), *i.e.*, Loestrin 24 and its AB-rated generic bioequivalents;
- d. whether the defendants unlawfully delayed or prevented generic manufacturers from coming to market in the United States;
- e. whether the defendants maintained Warner Chilcott's monopoly power by delaying generic entry;
- f. whether the activities of the defendants as alleged herein have substantially affected interstate commerce;
- g. whether, and to what extent, the defendants' conduct caused antitrust injury (*i.e.*, overcharges) to American Sales and the members of the class; and
- h. the quantum of overcharge damages to the class.

295. 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,

geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

296. American Sales knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. MONOPOLY POWER AND RELEVANT MARKET

297. At all relevant times, Warner Chilcott had monopoly power over oral contraceptives comprised of 24 norethindrone acetate/ethinyl estradiol tablets (containing 1 mg of norethindrone acetate and 20 mcg ethinyl estradiol) and 4 ferrous fumarate tablets (placebo) – *i.e.* Loestrin 24 and its AB-rated generic equivalents – because Warner Chilcott had the power to maintain the price of these products at supracompetitive levels without losing substantial sales to other oral contraceptive products.

298. A small but significant, non-transitory price increase by Warner Chilcott would not have caused a significant loss of sales so as to make the higher prices unprofitable.

299. 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.

300. Loestrin 24 is not interchangeable with any products other than AB-rated generic versions of Loestrin 24.

301. 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 its current prices of Loestrin 24 without losing substantial sales.

302. Warner Chilcott also sold branded Loestrin 24 at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

303. Warner Chilcott has had, and exercised, the power to exclude generic competition to branded Loestrin 24.

304. Warner Chilcott, at all relevant times, enjoyed high barriers to entry with respect to branded and generic Loestrin 24.

305. American Sales is not legally required to prove monopoly power circumstantially by defining a relevant product market, but American Sales alleges that the relevant market is Loestrin 24 and its AB-rated generic equivalents. During the period relevant to this case, the defendants have been able to profitably maintain the price of Loestrin 24 well above competitive levels.

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

307. Warner Chilcott's market share in the relevant market was 100% at relevant times.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 1 AGREEMENT RESTRAINING TRADE (Against Warner Chilcott and Watson)

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

309. In or about April 2009 and at times prior to the formal execution thereof, Warner Chilcott and Watson entered into the Watson Exclusion Payment Agreement, a

continuing illegal contract, combination and conspiracy in restraint of trade under which Warner Chilcott agreed to pay Watson substantial consideration in exchange for Watson's agreement to delay bringing its generic version of Loestrin to the market, the purpose and effect of which were to: (a) allocate 100% of the market for Loestrin products in the United States to Warner Chilcott; (b) prevent the sale of generic versions of Loestrin in the United States, thereby protecting Loestrin from generic competition for five years or more; (c) fix the price at which direct purchasers would pay for Loestrin products at supracompetitive levels; and (d) allocate 100% of United States generic Loestrin sales to Watson during the first 180 days of generic sales.

310. The Watson Exclusion Payment Agreement harmed plaintiff and the Class as set forth above.

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

312. Warner Chilcott and Watson are *per se* liable for the Watson Exclusion Payment Agreement or are liable under a "quick look" or rule of reason standard.

313. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

314. As a direct and proximate result of Warner Chilcott's and Watson's anticompetitive conduct, as alleged herein, plaintiff and the Class were harmed as aforesaid.

**CLAIM II: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE
(Against Warner Chilcott and Watson)**

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

316. At all relevant times, Warner Chilcott possessed substantial market power (*i.e.*, monopoly 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.

317. Through the overarching anticompetitive scheme, including the Watson Exclusion Payment Agreement, Warner Chilcott and Watson conspired to maintain Warner Chilcott's monopoly power in the relevant market in order to block and delay market entry of AB-rated generic versions of Loestrin 24. The unlawful Exclusion Payment Agreement between Warner Chilcott and Watson allocated all sales of Loestrin products in the United States to Warner Chilcott; delayed the sales of generic Loestrin products; and fixed the price at which plaintiff and the Class would pay for Loestrin at the higher, branded price; and allocated all sales of generic Loestrin in the United States to Watson during the first 180 days of generic sales.

318. The goal, purpose and/or effect of the Watson Exclusion Payment Agreement was to maintain and extend Warner Chilcott's monopoly power in the United States market for Loestrin products in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Watson Exclusion Payment Agreement prevented or delayed generic competition to Loestrin and enabled Warner Chilcott to continue charging supracompetitive prices for Loestrin without a substantial loss of sales.

319. Warner Chilcott and Watson knowingly and intentionally conspired to maintain and enhance Warner Chilcott's monopoly power in the relevant market.

320. Warner Chilcott and Watson specifically intended that the Watson Exclusion Payment Agreement would maintain Warner Chilcott's monopoly power in the relevant market, and injured plaintiff and the Class thereby.

321. Warner Chilcott and Watson each committed at least one overt act in furtherance of the conspiracy.

322. As a direct and proximate result of Warner Chilcott's and Watson's concerted conduct, as alleged herein, plaintiff and the Class were harmed as aforesaid.

**CLAIM III: VIOLATION OF 15 U.S.C. § 1
AGREEMENT RESTRAINING TRADE
(Against Warner Chilcott and Lupin)**

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

324. In or about October 2010 and at times prior to the formal execution thereof, Warner Chilcott and Lupin entered into the Lupin Exclusion Payment Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Warner Chilcott agreed to pay Lupin substantial consideration in exchange for Lupin's agreement to delay bringing its generic version of Loestrin to the market, the purpose and effect of which were to: (a) allocate 100% of the market for Loestrin products in the United States to Warner Chilcott; (b) prevent the sale of generic versions of Loestrin in the United States, thereby protecting Loestrin from generic competition for five years or more; and (c) fix the price at which direct purchasers would pay for Loestrin products at supracompetitive levels.

325. The Lupin Exclusion Payment Agreement harmed plaintiff and the Class as set forth above.

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

327. Warner Chilcott and Lupin are *per se* liable for the Lupin Exclusion Payment Agreement or are liable under a “quick look” or rule of reason standard.

328. There is and was no legitimate, nonpretextual, procompetitive business justification for the exclusion payment that outweighs its harmful effect. Even if there were some conceivable justification, the payment was not necessary to achieve such a purpose, nor was it the least restrictive means of achieving any such purported justification.

329. As a direct and proximate result of Warner Chilcott’s and Lupin’s anticompetitive conduct, as alleged herein, plaintiff and the Class were harmed as aforesaid.

**CLAIM II: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE
(Against Warner Chilcott and Lupin)**

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

331. At all relevant times, Warner Chilcott possessed substantial market power (*i.e.*, monopoly 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.

332. Through the overarching anticompetitive scheme, including the Lupin Exclusion Payment Agreement, Warner Chilcott and Lupin conspired to maintain Warner Chilcott’s monopoly power in the relevant market in order to block and delay market entry of AB-rated generic versions of Loestrin. The unlawful Exclusion Payment Agreement between Warner Chilcott and Lupin allocated all sales of Loestrin products in the United States to Warner Chilcott; delayed the sales of generic Loestrin products; and fixed the price at which plaintiff and

the Class would pay for Loestrin at the higher, branded price; and allocated all sales of generic Loestrin in the United States to Lupin during the first 180 days of generic sales.

333. The goal, purpose and/or effect of the Lupin Exclusion Payment Agreement was to maintain and extend Warner Chilcott's monopoly power in the United States market for Loestrin products in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Lupin Exclusion Payment Agreement prevented or delayed generic competition to Loestrin and enabled Warner Chilcott to continue charging supracompetitive prices for Loestrin without a substantial loss of sales.

334. Warner Chilcott and Lupin knowingly and intentionally conspired to maintain and enhance Warner Chilcott's monopoly power in the relevant market.

335. Warner Chilcott and Lupin specifically intended that the Watson Exclusion Payment Agreement would maintain Warner Chilcott's monopoly power in the relevant market, and injured plaintiff and the Class thereby.

336. Warner Chilcott and Lupin each committed at least one overt act in furtherance of the conspiracy.

337. As a direct and proximate result of Warner Chilcott's and Lupin's concerted conduct, as alleged herein, plaintiff and the Class were harmed as aforesaid.

**CLAIM V: VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION AND MONOPOLISTIC SCHEME
(Against Warner Chilcott)**

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

339. At all relevant times, Warner Chilcott possessed substantial market power (i.e., monopoly 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.

340. Through its overarching anticompetitive scheme, as alleged above, Warner Chilcott willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and thereby injured plaintiff and the Class.

341. It was Warner Chilcott's conscious object to further its dominance in the relevant market by and through the overarching anticompetitive scheme.

342. Warner Chilcott's scheme harmed competition.

343. There is and was no cognizable, non-pretextual procompetitive justification for Warner Chilcott's actions comprising the anticompetitive scheme that outweighs the scheme's harmful effects. Even if there were some conceivable such justification that Warner Chilcott were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

344. As a direct and proximate result of the Warner Chilcott's illegal and monopolistic conduct, as alleged herein, plaintiff and the Class were harmed.

**CLAIM VI: VIOLATION OF 15 U.S.C. § 2
ATTEMPTED MONOPOLIZATION
(Against Warner Chilcott)**

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

346. Warner Chilcott, through its overarching anticompetitive scheme, specifically intended to maintain monopoly power in the relevant market. It was Warner Chilcott's conscious objective to control prices and/or to exclude competition in the relevant market.

347. The natural and probable consequence of Warner Chilcott's overarching anticompetitive scheme, which was intended by it and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

348. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Warner Chilcott will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

349. As a direct and proximate result of Warner Chilcott's illegal and monopolistic conduct, Plaintiff and the Class were harmed.

**CLAIM VII: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE
(Against all Defendants)**

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

351. At all relevant times, Warner Chilcott possessed substantial market power (i.e., monopoly 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.

352. Through the overarching anticompetitive scheme, including the agreements (and attendant payments) between Warner Chilcott, on the one hand, and Watson and Lupin, on the other, the defendants conspired to maintain Warner Chilcott's monopoly power in the relevant market in order to block and delay market entry of AB-rated generic versions of Loestrin 24. The unlawful agreements between Warner Chilcott and the generic defendants allocated all sales of Loestrin 24 and its AB-rated generic equivalents in the United States to Warner Chilcott; delayed the sales of generic Loestrin 24 products; and fixed the price at which American Sales and members of the Class would pay for Loestrin 24 and/or its AB-rated generic equivalents at the higher, branded price.

353. The goal, purpose and/or effect of the conspiracy was to maintain and extend Warner Chilcott's monopoly power in the United States market for delayed-release esomeprazole magnesium in violation of Sherman Act Section 2, 15 U.S.C. § 2. The conspiracy

prevented and/or delayed generic competition to Loestrin 24 and enabled Warner Chilcott to continue charging supracompetitive prices for Loestrin 24 without a substantial loss of sales.

354. The conspiracy also enabled Warner Chilcott to switch prescriptions from Loestrin 24 to Lo Loestrin. In the absence of the conspiracy (and agreement from the generic defendants to stay off the market), Warner Chilcott would not have developed or marketed Lo Loestrin and switched a substantial portion of sales to that product and/or generic Loestrin 24 would have entered the market before Lo Loestrin, thereby impeding Warner Chilcott from switching prescriptions to Lo Loestrin.

355. Defendants knowingly and intentionally conspired to maintain and enhance Warner Chilcott's monopoly power in the relevant market.

356. Defendants specifically intended that their conspiracy would maintain Warner Chilcott's monopoly power in the relevant market, and injured American Sales and the Class thereby.

357. Each defendant committed at least one overt act in furtherance of the conspiracy, including:

- Warner Chilcott paid each generic defendant to stay off the market.
- Each generic defendant agreed to stay off the market until January 22, 2014.
- Warner Chilcott and Watson agreed that if another generic launched before January 22, 2014, Watson could also immediately come to market.
- Warner Chilcott and Watson agreed that if Warner Chilcott succeeded in stopping another generic from selling its competing product before January 22, 2014, then Watson would have to stop selling its generic product.
- Lupin accepted the entry date from the Warner Chilcott / Watson agreement, ensuring that both it and Watson would stay off the market until January 24, 2014 (barring a third generic coming to market).

- Lupin agreed to drop its patent challenges, including efforts to break the bottleneck created by the Warner Chilcott / Watson agreement.

358. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, Plaintiff and the Class were injured.

XI. DEMAND FOR JUDGMENT

WHEREFORE, American Sales, on behalf of itself and the Class, respectfully request that the Court:

- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare American Sales as a representative of the class;
- B. Enter joint and several judgments against the defendants and in favor of American Sales and the class;
- C. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and
- D. Award American Sales and the class their costs of suit, including reasonable attorneys' fees as provided by law.

XII. JURY DEMAND

359. Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed class, demand a trial by jury on all issues so triable.

Dated: May 13, 2013

Respectfully submitted,

/s/ Patrick Lynch

[Add Lynch Signature Block]

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- Lupin agreed to drop its patent challenges, including efforts to break the bottleneck created by the Warner Chilcott / Watson agreement.

358. As a direct and proximate result of the defendants' concerted conduct, as alleged herein, Plaintiff and the Class were injured.

XI. DEMAND FOR JUDGMENT

WHEREFORE, American Sales, on behalf of itself and the Class, respectfully request that the Court:

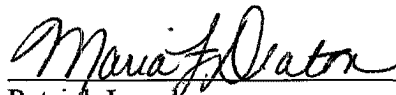
- A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the class, and declare American Sales as a representative of the class;
- B. Enter joint and several judgments against the defendants and in favor of American Sales and the class;
- C. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and
- D. Award American Sales and the class their costs of suit, including reasonable attorneys' fees as provided by law.

XII. JURY DEMAND

359. Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed class, demand a trial by jury on all issues so triable.

Dated: May 13, 2013

Respectfully submitted,



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*Counsel for Plaintiff American Sales and the
Proposed Class*

CERTIFICATE OF SERVICE

I, MARZIA DEATON, hereby certify that I caused a copy of this complaint to be filed electronically via the Court's electronic filing system on May 14, 2013. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Respectfully submitted,



CIVIL COVER SHEET

I. (a) PLAINTIFFS

American Sales Company, LLC

DEFENDANTS

CA 13-347M

(b) County of Residence of First Listed Plaintiff Erie County, NY
(EXCEPT IN U.S. PLAINTIFF CASES)County of Residence of First Listed Defendant Morris County, NJ
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Patrick C. Lynch
PATRICK LYNCH LAW FIRM
1 Park Row, 5th Floor
Providence, RI 02903 (401)274-3306NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE
LAND INVOLVED
DISTRICT OF RHODE ISLAND
Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- (For Diversity Cases Only)
- | | | | |
|---|---|---|---|
| Citizen of This State | PTF ☐ 1 DEF ☐ 1 | Incorporated or Principal Place of Business In This State | PTF ☐ 4 DEF ☐ 4 |
| Citizen of Another State | ☐ 2 ☐ 2 | Incorporated and Principal Place of Business In Another State | ☐ 5 ☐ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 ☐ 3 | Foreign Nation | ☐ 6 ☐ 6 |

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

Admiralty

- ☐ 340 Marine (Injury to Seamen)
- ☐ 120 Marine (Other)

Admin/Agency Appeals Other

- ☐ 890 Other Statutory Actions (APA Appeals, IDEA Appeals, Other)

Bankruptcy

- ☐ 422 Appeal 28 U.S.C. § 158
- ☐ 423 Withdrawal 28 U.S.C. § 157

Banks and Banking

- ☐ 140 Negotiable Instruments
- ☐ 430 Banks and Banking
- ☐ 875 Customer Challenge to Subpoena (12 U.S.C. § 3410)

Anti-trust

- ☒ 410 Anti-Trust

Construction Contracts

- ☐ 130 Miller Act
- ☐ 190 Other Contracts

Securities Law & Stockholder Suits

- ☐ 160 Stockholders' Suits
- ☐ 850 Securities/Commodities/Exchange

Other - Business/Comm.

- ☐ 196 Franchise
- ☐ 490 Cable/Satellite TV

Consumer Credit

- ☐ 371 Truth in Lending
- ☐ 480 Consumer Credit

- ☐ 190 Other Contracts

Constitutional Law

- ☐ 950 Constitutionality of State Statutes
- ☐ 440 Other Civil Rights (Constitutionality of Federal Statutes)

Elections and Voting

- ☐ 400 State Reapportionment
- ☐ 441 Voting

Other - Civil Rights

- ☐ 440 Other Civil Rights
- ☐ 443 Housing/Accommodations
- ☐ 444 Welfare
- ☐ 446 Americans with Disabilities

Civil Rights

Copyright & Trademark (Intellectual Property)

- ☐ 820 Copyright
- ☐ 840 Trademark

Employment Discrimination

- ☐ 442 Employment
- ☐ 445 Americans with Disabilities-Employment
- ☐ 440 Other - Civil Rights

ERISA

- ☐ 791 Employment Ret. Inc. Security Act

Other Employment Benefits

- ☐ 190 Other - Contract
- ☐ 442 Other - Employment

Environmental Law

- ☐ 893 Environmental Matters

Immigration

- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainees
- ☐ 465 Other Immigration Actions

Indian Law

- ☐ 890 Other Statutory Actions

Insurance

- ☐ 110 Insurance Contract

Labor and Occupational Safety

- ☐ 660 Occupational Safety/Health
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 730 Labor/Management Reporting and Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation

Miscellaneous Civil Cases

- ☐ 150 Recovery of Overpayment and Enforcement of Judgment (Collections)
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (excluding Veterans)
- ☐ 153 Recovery of Overpayment of Veterans' Benefits
- ☐ 370 Other Fraud
- ☐ 440 Other Civil Rights (Immigration/Deportation)
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 610 Agriculture
- ☐ 620 Other Food and Drug
- ☐ 625 Drug related seizure of property
- ☐ 630 Liquor Laws
- ☐ 640 Railroad and Truck

Miscellaneous Civil Cases Continued

- ☐ 650 Airline Regs.
- ☐ 690 Other (Forfeiture)
- ☐ 690 Other (Health Care)
- ☐ 810 Selective Service
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party (26 U.S.C. § 7609)
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination under Equal Access to Justice Act

Patents (Intellectual Property)

- ☐ 830 Patents

Prisoner Petitions

- ☐ 510 Motions to Vacate Sentence (2254)
- ☐ 510 Motions to Vacate Sentence (2255)
- ☐ 530 General (Habeas)
- ☐ 535 Death Penalty
- ☐ 540 Mandamus and Other
- ☐ 550 Civil Rights (1983)
- ☐ 555 Prison Conditions (1983)

Real and Personal Property

- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease and Ejectment
- ☐ 240 Torts to Land
- ☐ 290 All other Real Property
- ☐ 380 Other Personal Property Damage

RICO

- ☐ 470 RICO

Social Security

- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Mass Torts

- ☐ 360 Other Personal Injury

Products Liability

- ☐ 195 Contract Product Liability
- ☐ 245 Tort Product Liability
- ☐ 315 Airplane Product Liability
- ☐ 345 Marine Product Liability
- ☐ 355 Motor Vehicle Product Liability
- ☐ 365 Personal Injury Product Liability
- ☐ 385 Property Damage Product Liability

Professional Malpractice

- ☐ 362 Personal Injury - Med. Malpractice

Motor Vehicle Accidents/Slip and Fall

- ☐ 350 Motor Vehicles
- ☐ 360 Other Personal Injury

Other Torts and Personal Injury incl. Asbestos cases

- ☐ 360 Other Personal Injury (Fed. Tort Claims Act)
- ☐ 310 Airplane
- ☐ 320 Assault, Libel and Slander
- ☐ 330 Federal Employers' Liability
- ☐ 360 Other Personal Injury
- ☐ 368 Asbestos Personal Injury

Torts and Personal Injury

I. ORIGIN (Place an "X" In One Box Only)

☒ 1
Original
Proceeding☐ 2
Removed from
State Court☐ 3
Remanded from
Appellate Court☐ 4
Reinstated or
Reopened☐ 5
Transferred from
another district
(Specify)☐ 6
Multidistrict
Litigation☐ 7
Appeal to District Judge
From Magistrate Judgment

II. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

Sherman Act 15 U.S.C. Sections 1 & 2

Brief description of cause:

Pharmaceutical anti-trust case, alleging delayed entry of
generic competitionIII. REQUESTED IN
COMPLAINT☒ Check if this is a Class Action
Under F.R.C.P. 23

DEMAND \$

JURY DEMAND: ☒ Yes ☐ No
(Check YES only if demanded in complaint)IV. RELATED CASE(S)
IF ANYJUDGE John J. McConnell, Jr.DOCKET NUMBER 1:13-cv-00307-M-PAS

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

Date

5/14/13

Signature of Attorney of Record

Maria F. Deaton

Patrick C. Lynch, Esq.

Maria F. Deaton, Esq.

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44

Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the Cover Sheet.

- I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.
- IV. NATURE OF SUIT: Place an X in the appropriate box. Make sure to select the Nature of Suit from the category which best describes the primary cause of action found in your complaint. You must select only one nature of suit.
- VIII. RELATED CASES, IF ANY: This section of the JS-44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

FOR OFFICE USE ONLY

Receipt # _____ Amount _____ Applying IFP _____ Judge _____ Mag. Judge _____

Court Name: U.S. District Court for RI
Division: 1
Receipt Number: 14670010932
Cashier ID: jduhamel
Transaction Date: 05/14/2013
Payer Name: Patrick Lynch Law Firm LLC

CIVIL FILING FEE
For: Patrick Lynch Law Firm LLC
Case/Party: D-RIX-1-13-CV-000347-001
Amount: \$400.00

CHECK
Amt Tendered: \$400.00

Total Due: \$400.00
Total Tendered: \$400.00
Change Amt: \$0.00

Patrick Lynch Law Firm LLC

One Park Row - Suite 5

Providence, RI 02903

filing fee for CA 13-347M