

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ROCHESTER DRUG CO-OPERATIVE,
INC., on behalf of itself and all others
similarly situated,

Plaintiff,

v.

ENDO PHARMACEUTICALS INC.,
TEIKOKU PHARMA USA, INC.,
TEIKOKU SEIYAKU CO., LTD, WATSON
PHARMACEUTICALS, INC., WATSON
LABORATORIES, INC., and ACTAVIS,
plc.,

Defendants.

Civil Action No.

CLASS ACTION
JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

Plaintiff Rochester Drug Co-Operative, Inc. (“RDC” or “Plaintiff”), brings this class action on behalf of itself and all others similarly situated against Defendants Endo Pharmaceuticals Inc. (“Endo”), Teikoku Pharma USA (“Teikoku Pharma”), Teikoku Seiyaku Co. (“Teikoku Seiyaku” and together with Teikoku Pharma “Teikoku” and collectively with Endo, “Endo/Teikoku”), Watson Pharmaceuticals, Inc., and Actavis, plc, formerly known as Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively, “Watson”) (together with Endo/Teikoku, the “Defendants”) and alleges as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiff on behalf of a Class of direct purchasers of lidocaine patch 5%, sold by Endo under the brand name Lidoderm. Lidoderm is a lidocaine-containing pain patch for the treatment of pain associated with post-herpetic neuralgia.

Plaintiff seeks overcharge damages arising out of Endo/Teikoku's unlawful agreement with Watson not to compete in the market for lidocaine patch 5%.

2. On May 28, 2012, Endo and Teikoku entered into an unlawful non-competition agreement with Watson, agreeing to pay Watson substantial sums in exchange for Watson's agreement to delay marketing its less expensive generic version of Lidoderm for over a year, *i.e.*, until September 15, 2013 (the "Agreement"). In compliance with the Agreement, even though Watson was granted final FDA approval to launch its less-expensive generic Lidoderm patch on August 23, 2012, Watson did not come to market until just after September 15, 2013.

3. As part of the Agreement, Endo and Teikoku promised not to launch an authorized generic to compete with Watson's generic Lidoderm for 7.5 months after Watson launches its generic.

4. But for Defendants' unlawful agreement, one or more generic versions of Lidoderm would have been marketed in the United States beginning in August 2012. Thus, absent Defendants' unlawful agreement, Plaintiff and the members of the Class would have been able to satisfy their lidocaine patch 5% requirements at significantly lower prices substantially earlier than they did, rather than being forced to pay for branded Lidoderm at higher prices because of the unlawful agreement. Lidoderm sales for the twelve months ending March 31, 2012 were approximately \$1.2 billion.

5. Defendants' unlawful agreement was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patch 5% in the United States; (b) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products; (d) permit Endo/Teikoku to maintain a monopoly in the

United States for lidocaine patch 5%; and (e) allocate 100% of the United States lidocaine patch 5% market to Endo/Teikoku.

6. As alleged in more detail below, Defendants violated §§ 1 and 2 of the Sherman Act through their anticompetitive agreement to improperly maintain and extend Endo/Teikoku's market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of lidocaine patch 5%.

II. JURISDICTION AND VENUE

7. 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 Plaintiff and members of the Class (defined below) resulting from Defendants' unlawful foreclosure of the United States market for lidocaine patch 5%. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

8. Defendants transact business within this district, and they carry out interstate trade and commerce in substantial part in this district and/or have an agent and/or can be found in this district. Defendant Endo has its principal place of business in this district. Venue is therefore appropriate within this district under section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

III. PARTIES

A. Plaintiff

9. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the class period, as defined

below, RDC purchased branded Lidoderm directly from Endo, and purchased generic Lidoderm directly from Actavis, and was injured as a result of Defendants' unlawful conduct.

B. Defendants

10. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania. Endo markets and sells Lidoderm throughout the United States.

11. Defendant Teikoku Seiyaku is a company organized and existing under the laws of Japan, having its principal place of business in Higashikagawa, Kagawa, Japan. Teikoku Seiyaku is the owner, assignee or licensee of U.S. Patent No. 5,827,529 (the "'529 patent") over which Endo and Teikoku sued Watson. Teikoku Seiyaku manufactures Lidoderm in Japan for commercial sale in the United States by Endo under a Manufacturing and Supply Agreement with Endo. Endo pays Teikoku Seiyaku royalties under that agreement.

12. Defendant Teikoku Pharma is a California corporation, having its principal place of business at 1718 Ringwood Avenue, San Jose, California. Teikoku Pharma is a wholly-owned subsidiary of Teikoku Seiyaku, and is the holder of the New Drug Application for Lidoderm.

13. Actavis, plc is incorporated under the laws of Ireland, having its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Actavis, plc also has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. as a result of Watson Pharmaceuticals, Inc.'s acquisition of Actavis Group in or around October 2012. Actavis, Inc. changed its name to Actavis, plc on or about October 1, 2013.

14. Defendant Watson Pharmaceuticals, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Effective on or about

January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. which later became Actavis, plc.

15. Defendant Watson Laboratories, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Defendant Watson Laboratories, Inc. was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc.

16. Defendants Actavis, plc, Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. are collectively referred to herein as “Watson.” Watson is engaged in marketing, production and distribution of generic pharmaceutical products.

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

18. With respect to all of the conduct complained of below, at all relevant times Endo acted in concert with the Teikoku Defendants.

IV. CLASS ACTION ALLEGATIONS

19. Plaintiff brings this action on behalf of itself and, under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, as representative of a Class defined as follows:

All persons or entities in the United States who purchased branded and/or generic Lidoderm directly from any of the Defendants at any time during the period August 23, 2012 through the date on which the anticompetitive effects of Defendants’ challenged conduct cease (the “Class”).

Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, and affiliates, and all federal governmental entities.

20. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes the Class numbers in at least the dozens. Further, the Class is readily identifiable from information and records in the possession of Defendants. Direct notice to the members of the Class should be feasible upon obtaining the relevant information and records in the possession of Defendants.

21. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by the same wrongful conduct by Defendants, *i.e.*, they paid artificially inflated prices for lidocaine patch 5% and were deprived of the benefits of competition from less-expensive generic versions of Lidoderm as a result of Defendants' wrongful conduct.

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

23. Plaintiff is 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 in the pharmaceutical industry.

24. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

25. Questions of law and fact common to the Class include:

- a. whether Defendants conspired to suppress generic competition to Lidoderm;
- b. whether, pursuant to the Agreement, Watson agreed to delay its entry into the market with generic Lidoderm;

- c. whether, pursuant to the Agreement, Endo and Teikoku compensated Watson;
- d. whether Defendants' challenged conduct suppressed generic competition to Lidoderm;
- e. whether Defendants' challenged conduct harmed competition in the market(s) in which Lidoderm is sold;
- f. whether Endo possessed market or monopoly power over Lidoderm;
- g. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
- h. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;
- i. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and the members of the Class in the nature of overcharges; and
- j. the quantum of overcharges paid by the Class in the aggregate.

26. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

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

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

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

29. NDAs that meet certain requirements are eligible for exclusivities that prevent FDA from approving applications for the same drug for prescribed periods of time. One example is Orphan Drug Exclusivity, which is available for drugs that treat rare diseases or disorders. This exclusivity prohibits FDA approval of other applications for the same drug for seven years. 21 C.F.R. § 316.31.

30. When FDA approves a brand manufacturer’s NDA, the brand manufacturer may list in the Orange Book any patent that claims either the approved drug or approved methods of use of the drug and could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand drug prior to the expiration of the listed patent(s). Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

31. The FDA relies completely on the brand manufacturer’s truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the

manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

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

33. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical — or bioequivalent — to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. “Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to

the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.’”

See <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm>.

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

2. Paragraph IV Certifications

35. 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. Under the Hatch-Waxman Amendments, a generic manufacturer’s ANDA must contain one of four certifications:

- a. that no patent for the brand drug has been filed with the FDA (a “Paragraph I certification”);
- b. that the patent for the brand drug has expired (a “Paragraph II certification”);
- c. that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a “Paragraph III certification”); or
- d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer’s proposed product (a “Paragraph IV certification”).

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

37. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. The first generic applicant often receives 180 days of market exclusivity (unless some forfeiture event, like that discussed below, occurs), meaning that the FDA will not approve any other ANDA for that same generic drug for at least six months. This allows the first filer to be free from competition from other generic companies for at least six months, if there are other ANDA applicants that would otherwise be entitled to final FDA approval during that time.

3. Authorized Generics and No-Authorized Generic Agreements

38. In an increasing number of instances, a brand company makes a reverse payment to a first-filing generic company in the form of the brand company’s promise not to launch an “authorized generic” version of the branded drug during the first 180 days of generic marketing

(and sometimes longer). 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 generic version of its own brand drug.

39. For the brand company, an authorized generic launched during the first 180 days of generic marketing (or longer) provides a low cost, low risk means to regain some of the revenue lost from the termination of brand exclusivity that would otherwise go to the generic first-filer. For the generic manufacturer enjoying exclusivity as the first generic to be marketed, however, an authorized generic launch has a substantial negative impact on its revenue. Generic companies generally make about 80% of their total income on a given generic product during the period that they are the sole generic equivalent of the corresponding branded drug, and an authorized generic, when launched during that time, is typically priced competitively as against the non-authorized generic, and typically captures 50% of total generic sales during that period. The promise of no authorized generic during the initial period of generic marketing is thus a very valuable payment to the generic company that is the sole generic entrant during that time. That promise doubles the revenues and profits the generic company makes from the product during that time.

40. To prevent this 50% loss of revenue from an authorized generic launch, a generic company that will be the initial generic entrant for the corresponding branded drug may be willing to delay its entry in return for the brand company's agreement to forego its own revenue stream and forebear from launching an authorized generic during the initial period of generic marketing, as Endo/Teikoku agreed to do here. Although a brand company will lose authorized generic product revenue and profits when making a no-authorized generic agreement, it retains far more in

branded profits and sales from paying a generic company to delay market entry using such a no-authorized generic agreement.

41. In a report by the Federal Trade Commission (“FTC”) issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (“*Authorized Generic Drugs*”), the FTC concluded that no-authorized generic agreements 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% during the first 180 days of generic marketing. The FTC found that a generic company makes significantly less when competing with an authorized generic because (1) the authorized generic takes a significant share of generic sales away from the first-filer, and (2) wholesale and retail prices decrease when the first-filer faces an authorized generic. The FTC noted that: “there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry. These agreements can be part of ‘pay-for-delay’ patent settlements, which have long concerned the Commission.” See *Authorized Generic Drugs* at vi, available at <http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf>. The FTC found that an authorized generic can cut a first-filer’s generic revenue by more than half during the first 180 days of generic marketing, and forces generic prices down. *Id.* at iii, vi, 41-48, 57-59. A 2006 study sponsored by the brand drug company trade association, PhRMA, similarly had found that an authorized generic results in lower generic prices. Such an agreement between horizontal competitors injures consumers twice over, first by prolonging the period during which only the high priced brand is available, then

ensuring that generic prices are artificially inflated when generic competition finally begins by keeping the authorized generic off the market.

42. For the first-filer generic like Watson, of a branded product like Lidoderm, the difference between selling the only generic product and competing against an authorized generic for the first months of generic marketing can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic. No-authorized generic agreements like the one between Endo/Teikoku 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.

B. Generic Versions of Brand Drugs are Significantly Less Expensive, and Take Significant Sales Directly From the Corresponding Brand Versions.

43. Typically, AB-rated generics are priced significantly below their branded counterparts. Because of the price differentials and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted by pharmacists who are presented with a prescription for the brand counterpart. In particular, generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by FDA. In every state, pharmacists are permitted (and in some states, required) to substitute a generically-equivalent product for the brand product prescribed, unless the doctor has indicated that the prescription for the brand product must be "dispensed as written." As more generic manufacturers enter the market, prices for generic versions of a drug predictably decrease even further because of competition among the generic manufacturers. Pharmacy substitution, and thus the loss of sales volume by the brand drug to the corresponding generic, thereby accelerates. According to a recent FTC staff study, within one year of generic entry, 90% of prescriptions are filled with the brand's

generic substitute, 85% of the pre-entry branded drug price. *“Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions,”* FTC Staff, January 2010 at 8.

44. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price. However, until a generic manufacturer enters the market, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand drug, and therefore the brand manufacturer can continue to charge supracompetitive prices profitably without losing all or a substantial portion of its brand sales. Consequently, brand manufacturers have a strong incentive to use various tactics, including entry into reverse payment agreements as in this case, to delay the introduction of generic competition into the market.

VI. FACTUAL ALLEGATIONS

A. Background

1. Approval of Brand Lidoderm and the Relevant Patents

45. Lidoderm is a prescription lidocaine-containing (5%) pain patch used to treat pain associated with post-herpetic neuralgia. The active ingredient in Lidoderm is lidocaine. Its pharmacological profile, and thus its side effect and efficacy profile, is different from other pharmaceuticals that are used to treat the same or similar conditions. Those other drugs are not AB-rated to Lidoderm, cannot be automatically substituted for Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Lidoderm, and thus are not economic substitutes for, nor reasonably interchangeable with, Lidoderm.

46. On March 19, 1999, FDA approved NDA 21-153, submitted by Hind Health Care, Inc. (“Hind”), which sought to market an adhesive patch containing 5% lidocaine under the brand name Lidoderm for the treatment of pain associated with post-herpetic neuralgia. Lidoderm was

awarded Orphan Drug Exclusivity by FDA, meaning that no generic competitor could get FDA approval for generic Lidoderm until March 2006.

47. In 1998, Hind had granted to Endo the exclusive right to market and distribute Lidoderm in the United States. Hind subsequently transferred full ownership of and responsibility for the Lidoderm NDA to Teikoku Pharma, effective June 1, 1999. Endo launched Lidoderm in the United States in 1999.

48. Endo and Teikoku owned or obtained assignments of or licenses to a number of patents associated with Lidoderm.

49. Subsequently, Teikoku listed several patents in the Orange Book as covering Lidoderm. As of January 2010 (the date upon which Watson filed ANDA No. 20-675, the first filed ANDA as to Lidoderm), Teikoku had three patents listed in the Orange Book. The first was U.S. Patent No. 5,411,738 (the “’738 patent”), which is a method of use patent for treating certain types of pain with lidocaine using a topical delivery mechanism and a gel formulation of lidocaine. The second was U.S. Patent No. 5,601,838 (“the ’838 patent”), which is a method of use patent for treating certain types of pain with lidocaine. The ’738 and ’838 patents both were assigned to Hind, both expired on May 2, 2012, and are referred to collectively as the “Hind patents.”

50. The third patent that Teikoku listed in the Orange Book as covering Lidoderm was U.S. Patent No. 5,827,529 (the “’529 patent”), which is a formulation patent for a lidocaine patch. This patent was assigned to Teikoku, and is set to expire on October 17, 2015.

51. The ’529 patent, titled “External Preparation for Application to the Skin Containing Lidocaine,” issued on October 27, 1998, from an application filed on June 10, 1994. That application was a continuation of an application filed on March 30, 1992.

52. The '529 patent claims foreign priority to Japanese Application No. 3-067353, filed March 30, 1991.

53. The '529 patent contains six claims directed generally to a hydrogel transdermal patch containing the active ingredient lidocaine and inactive ingredients or excipients.

54. Claim 1 of the '529 patent claims a patch comprising "a drug-retaining layer placed on a support," in which the drug-retaining layer comprises an "adhesive gel base and 1 to 10% by weight of lidocaine." The claimed "adhesive gel base" consists of three components within specific percentage weight ranges: (i) "0.5 to 50% by weight of a water-soluble high molecular weight substance"; (ii) "30 to 70% by weight of water"; and (iii) "1 to 70% by weight of a water-retaining agent."

55. Endo subsequently obtained additional patents from LecTec Corporation ("LecTec") that it and Teikoku claim cover Lidoderm. In July 2008, LecTec had filed patent infringement litigation against Endo and other manufacturers of medicinal patch products in the United States District Court for the Eastern District of Texas (the "LecTec Litigation") over U.S. Patent No. 5,536,263 (the "'263 patent"), and U.S. Patent No. 5,741,510 (the "'510 patent"), both of which are patents for a medicinal adhesive patch. Each of these patents expires on March 30, 2014.

56. Endo settled the litigation with LecTec in November 2009 by paying LecTec \$23 million in exchange for exclusive licenses to the '263 and the '510 patents for use in the field of prescription pain medications and treatment.

57. Almost a year later, in or about October 2010, Endo granted Teikoku a sublicense under the '510 patent to make and sell prescription pain medications that contain 5% lidocaine in patch dosage form, including Lidoderm.

58. In or about November 2010, Teikoku submitted the '510 patent to the FDA for listing in the Orange Book with respect to Lidoderm.

59. As of January 2011, Endo/Teikoku had four patents listed in the Orange Book related to Lidoderm: the two Hind patents (which expired in May 2012), the '529 patent, and the '510 patent.

60. In or about May 2011, in exchange for \$2 million, Endo acquired from LecTec full title to the '263 patent, the '510 patent and three other patents. The three other patents were U.S. Patent No. 6,096,333 (the "'333 patent"), (ii) U.S. Patent No. 6,096,334 (the "'334 patent"); and (iii) U.S. Patent No. 6,361,790 (the "'790 patent") (collectively with the '263 and the '510 patents, "the Rolf patents," named for one of the inventors). These three patents all expire on March 30, 2014, and cover methods of formulating a medicinal adhesive patch. Other than the '510 patent, none of the Rolf patents has been listed in the Orange Book with respect to Lidoderm.

2. Watson's ANDA

61. On or about January 14, 2010, Watson notified Teikoku that it had filed ANDA No. 20-675, seeking to market a generic version of Lidoderm. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Lidoderm product would not infringe any claim of the '529 patent, and/or that the '529 patent was invalid and/or unenforceable. Watson was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to Lidoderm.

62. Watson did not submit Paragraph IV certifications as to the Hind patents, which were to expire on May 2, 2012. As a result, FDA could not approve Watson's ANDA for generic Lidoderm until the Hind patents expired on May 2, 2012.

63. Watson made no certification to any of the Rolf patents because, as of January 14, 2010, the Rolf patents were not listed in the Orange Book.

64. FDA granted final approval to Watson's ANDA on August 23, 2012, but Watson ultimately did not launch its approved generic Lidoderm product until September 16, 2013 because of the unlawful Agreement with Endo/Teikoku.

3. The Patent Litigation Against Watson

65. On February 19, 2010, Endo and Teikoku filed suit against Watson in the United States District Court for the District of Delaware, alleging that Watson's generic Lidoderm product would infringe the '529 patent (the "'529 Litigation"). As a result of the filing of the '529 Litigation, a 30-month stay applied to Watson's ANDA, precluding FDA from approving Watson's ANDA until that stay expired in July 2012 or entry of a final judgment that the '529 patent was invalid, unenforceable, and/or not infringed, whichever came first.

66. Watson raised numerous defenses, including that the '529 patent was invalid and/or unenforceable. As the '529 Litigation moved toward trial, Endo and Teikoku, fearing that the patent would not prevent generic competition, acquired additional patents and filed yet another suit against Watson.

67. On or about June 29, 2011, Endo filed a second suit against Watson in the United States District Court for the District of Delaware (*Endo Pharm. Inc. v. Watson Lab., et al.*, 11-cv-00575-GMS) (the "Rolf Patent litigation"), alleging that Watson's generic Lidoderm product would infringe three of the Rolf patents, the '333 patent, the '334 patent, and the '510 patent. Only the '510 patent was ever listed in the Orange Book. Because the Rolf patents had not been listed in the Orange Book when Watson filed its ANDA, this suit did not result in a 30-month Hatch-Waxman stay.

a. The '529 Litigation

68. The '529 Litigation proceeded to a bench trial in February 2012, in which Watson presented evidence of the invalidity of the '529 patent, as well as evidence that Watson's generic did not infringe the patent. By the end of the trial, the infirmities of the '529 patent had been laid bare.

69. By the time of the bench trial, Endo and Teikoku were well aware that the '529 patent would not survive the numerous defenses that Watson asserted, exposing that the patent was invalid or unenforceable and did not cover either the brand product or Watson's generic product.

i. The '529 Patent Was Invalid

70. The same hydrogel transdermal patch technology claimed in the '529 patent was disclosed in multiple pieces of prior art which were not disclosed to the patent examiner, but which were well known to Endo/Teikoku (the "Teikoku Prior Art"). Each discloses a hydrogel transdermal patch formulation substantially similar to that claimed in the '529 patent, except for the active pharmaceutical ingredient.

71. Each discloses an "adhesive gel base" consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a water-retaining agent, all of which fall within the percentage ranges claimed in the '529 patent. And, each shares at least one inventor with the '529 patent, and also shares the same applicant, prosecuting attorneys or assignee with the '529 patent.

72. During the prosecution of the '529 patent, the PTO rejected the patent five times noting that because lidocaine was conventionally used in transdermal patches, it would have been obvious to place lidocaine into available prior art patches. The PTO never cited, and was unaware of, the Teikoku Prior Art. The applicants consistently distinguished other prior art patches cited by the Examiner, arguing that the patch in the '529 patent was "unique." The applicants never

disclosed the Teikoku Prior Art to the PTO, nor did it disclose Teikoku's own prior art patent (U.S. Patent No. 4,695,465) on the same patch technology that was the subject of the '529 patent, which would have showed that the patch technology in the '529 patent was not unique, and in fact had been previously patented.

73. Each of these prior art references is prior art to the '529 patent because each was publicly available and accessible more than one year before the March 30, 1991 priority date of the '529 patent. Each of the prior art references predates the priority date of the '529 patent by over a year, and thus invalidates the '529 patent.

ii. The '529 Patent Was Not Infringed

74. In addition to being invalid as obvious, the '529 patent did not cover Lidoderm and is not infringed by Watson's generic equivalent. The patch formulation disclosed in the '529 patent includes a water soluble high molecular weight substance, water, and a water-retaining agent. The water soluble high molecular weight substance and the water-retaining agent must be from the groups listed in the patent. The groups listed in the '529 patent are known as Markush groups. "A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." *Endo Pharm., Inc. et al., v. Watson Lab., Inc.*, slip op. at 1 n.1, No. 10-138 (GMS) (D. Del. June 27, 2011) (quoting *Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

75. In the '529 patent, the first Markush group related to "a water-soluble high molecular weight substance selected from the group consisting of gelatin, starch, agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin, methylcellulose, methylcellulose sodium, carboxymethylcellulose, carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl

pyrrolidone, copolymer of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and locust bean gum.”

76. The second Markush group related to “a water-retaining agent selected from the group consisting of ethylene glycol, diethylene glycol, polyethylene glycol, glycerin, sorbitol, mannitol, propylene glycol and 1,3-butylene glycol.”

77. As the District Court found in the *Markman* decision construing those two patent terms, Federal Circuit precedent from 2003 clearly established that both of the relevant Markush groups in the ’529 patent were limited to one and only one of the listed alternatives. *Endo Pharm., Inc. et al., v. Watson Lab., Inc.*, slip op. at 1 n.1-2. Under Federal Circuit precedent, the patent must be interpreted to cover a product which contains only *one* of the substances from each of the two Markush groups.

78. Both Lidoderm and Watson’s generic Lidoderm product contain at least *five* water-soluble high molecular weight substances, and *three* water-retaining agents. Thus, they are outside the scope of the ’529 patent because they each contain more than one substance from each group.

b. The Rolf Patent Litigation

79. The Rolf patents asserted in the second litigation also afforded Endo/Teikoku no protection from generic competition. Watson had raised defenses and counterclaims alleging those patents were invalid and/or unenforceable and that its product did not infringe them. The Rolf Patent Litigation barely proceeded past the pleading stage. The Rolf patents posed no reasonable risk to Watson of patent infringement liability.

80. Of the Rolf patents, only the ’510 patent had been asserted by its previous owner, LecTec, against Endo with respect to its Lidoderm product in the LecTec Litigation in 2008.

81. And, as Endo and Teikoku learned from the LecTec Litigation, the '510 patent was subject to a strong invalidity challenge as being invalid as obvious in view of prior art references that were not submitted to the PTO during the prosecution of the '510 patent.

82. Watson was aware of the infirmities of the '510 patent from the publicly filed pleadings in the LecTec Litigation.

83. The '333 and '334 patents also afforded no reasonable infringement threat to Watson. Indeed, LecTec had not even sued Endo for infringement of the '333 and '334 patents with respect to Lidoderm. When Endo ultimately settled the LecTec Litigation in November 2009, it obtained licenses only to the '263 and '510 patents. At that time, neither LecTec nor Endo believed that licenses to the '333 and '334 patents were relevant to the use, manufacture, or sale of Lidoderm. Watson's patch similarly would not infringe the '333 and '334 patents.

84. Indeed, Endo did not obtain the rights to the '333 and '334 patents until May 2011, when it bought the rights to all of the Rolf patents from LecTec for just \$2 million.

B. Endo, Teikoku and Watson Enter the Unlawful "Pay for Delay" Agreement

85. On or about May 28, 2012, Endo, Teikoku and Watson entered into an agreement ending the patent litigation related to Lidoderm between Endo/Teikoku and Watson. The Agreement resolved the litigation as to the '529 patent and all of the Rolf patents.

86. Under the Agreement, Watson Laboratories, Inc., on behalf of itself and its Affiliates, including its parent company, Watson Pharmaceuticals, Inc., agreed that it, and its Affiliates, agreed to delay launching its generic Lidoderm product until September 15, 2013, unless otherwise specifically authorized by the Agreement. Watson Pharmaceuticals, Inc. also agreed through its wholly owned subsidiary, Watson Laboratories, Inc., to be bound by the terms and conditions of the Agreement.

87. As the *quid pro quo* for Watson's promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo and Teikoku agreed to pay Watson at least \$96 million (in the form of branded Lidoderm at no cost to Watson in) at the rate of \$12 million per month from January 1, 2013 through August 1, 2013. Watson was free to sell the brand Lidoderm product and retain the full proceeds of those sales. This payment was no different than if Endo and Teikoku had paid Watson \$96 million in cash.

88. Through the Agreement, Defendants ensured that Watson's sales of the product would not result in price competition, but rather that Watson would sell the branded Lidoderm product at the same supracompetitive prices at which Endo had been selling it. The Agreement provided that Watson would honor all of Endo's price-related contracts with its wholesalers.

89. Additionally, Endo and Teikoku agreed to delay launching an authorized generic for up to 7.5 months, so long as Watson was the sole generic Lidoderm product on the market. Endo and Teikoku were otherwise ready, willing, and able to launch an authorized generic version of Lidoderm simultaneously with Watson's entry. This latter promise had a cash value to Watson in the hundreds of millions of dollars. Endo and Teikoku's agreement not to launch an authorized generic meant that Watson would be the sole generic on the market for up to 7.5 months, so long as no other ANDA filer obtained FDA approval and entered the market, and Watson could therefore maintain a supracompetitive generic price, obtain all generic sales, and earn higher profits than it otherwise would have earned, all at the expense of Plaintiff and the members of the Class.

90. Endo and Teikoku sacrificed profit by their agreement not to launch an authorized generic. Absent the unlawful Agreement, it would make economic sense for Endo/Teikoku to launch an authorized generic during Watson's period of exclusive marketing so that Endo/Teikoku

could retain some of the sales that Watson's less expensive generic otherwise would capture. As alleged above, an authorized generic product typically captures approximately 50% of the generic sales during first 180 days of generic marketing.

91. The total payment flowing from Endo and Teikoku to Watson had a cash value in the hundreds of millions of dollars, and had no explanation or justification other than to induce Watson to stay out of the lidocaine patch 5% market and share monopoly profits among Defendants. This large, unjustified reverse payment had no rational connection to, and far exceeds, any approximation of the costs of continuing the patent litigation. The reverse payment was not consideration for the fair value of any services provided by Watson to Endo or Teikoku. Indeed, Watson was not required to perform any services for Endo or Teikoku under the unlawful Agreement. The Agreement had no value to Endo in the form of a distribution arrangement, and Endo had no need for any such services for Lidoderm in any event.

92. Absent Endo and Teikoku's unlawful payments to Watson, any agreement settling the patent litigation would have resulted in much less delay of Watson's generic entry than with the payment. Under such an agreement, or even without one, Watson would have launched much earlier than September 2013.

93. Endo/Teikoku used the strength of its wallet as opposed to the strength of its patents to obtain the agreement of Watson not to launch its generic Lidoderm product until September of 2013. In light of the fact that a ruling that the '529 patent was invalid or did not cover Lidoderm or a generic version of Lidoderm would have eliminated any reasonable possibility of keeping generic versions of Lidoderm from swiftly eradicating the vast majority of sales from Lidoderm, Endo/Teikoku agreed to share their monopoly rents with Watson as the *quid pro quo* for Watson's

agreement not to compete with Endo/Teikoku in the lidocaine patch 5% market until September 15, 2013.

94. The evidence amassed during and prior to the patent litigations provided Endo and Teikoku with ample notice that their patents would not withstand scrutiny and provided no protection from generic entry. Moreover, the millions of dollars that Endo paid to Watson as part of the unlawful Agreement “provide a workable surrogate for [the] patent[s’] weakness[es].” *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223, 2236-37 (2013). “An unexplained reverse payment”, like the payment at issue here, “itself would normally suggest that the patentee has serious doubts about the patent’s survival.” *Id.* at 2236.

C. Anticompetitive Purpose and Effect of Defendants’ Conduct

95. The unlawful Agreement has enabled Defendants to: (a) delay and/or preclude the entry of less expensive generic versions of Lidoderm products in the United States; (b) delay and/or suppress the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market coincident with initial generic competition (and, at the latest, at a significantly earlier time than 7.5 months after Watson’s September 2013 launch); (c) fix, raise, maintain or stabilize the price of lidocaine patch 5% products; (d) maintain a monopoly in the U.S. market for lidocaine patch 5% products; and (e) allocate 100% of the U.S. market for lidocaine patch 5% to Endo/Teikoku.

96. But for the unlawful Agreement: (i) Watson would have begun selling its generic version of Lidoderm when or shortly after it received FDA approval on August 23, 2012; (ii) Endo/Teikoku would have launched an authorized generic lidocaine patch 5%; and (iii) an increasingly competitive market for lidocaine patch 5% would have thereafter emerged as additional generic manufacturers entered the market.

97. Watson would have launched its generic product despite any other patents that Endo/Teikoku may have claimed covered Lidoderm, and prior to resolution of any litigation over the Rolf patents. None of the patents other than the '529 patent discussed above was listed in the Orange Book when Watson filed its ANDA. Thus, Watson was not required to certify to those patents under Hatch-Waxman, and any litigation filed over those patents would not, and could not, result in a 30 month Hatch-Waxman stay of FDA approval of Watson's ANDA. Thus, patent litigation relating to patents other than the '529 patent would have been no impediment to approval of Watson's ANDA on August 23, 2012. Given the defects in the Rolf patents, Watson would have launched upon final FDA approval even in the absence of a court ruling on those patents. Once Watson obtained FDA approval of its ANDA, it was free to launch, and Watson would have launched its generic Lidoderm immediately.

98. Alternatively, but for the unlawful Agreement: (i) Endo, Teikoku and Watson would have entered a procompetitive settlement agreement under which Watson would have entered the market much earlier than September 2013 and Watson would not have received a large payment from Endo and Teikoku; (ii) Endo/Teikoku would have simultaneously launched an authorized generic lidocaine patch 5%; and (iii) an increasingly competitive market for lidocaine patch 5% would have thereafter emerged as additional generic manufacturers entered the market, further driving down the price of lidocaine patch 5%.

99. Watson had been telling Wall Street analysts in late 2011 and early 2012 that it was pursuing its ANDA, that it was closely monitoring the progress of the ANDA and expected approval in 2012, that its efforts to increase capacity were well underway, and it expected to be "ready to go at the earliest possible time to launch the product."

100. Defendants' unlawful actions have delayed or prevented the sale of generic Lidoderm in the United States, and unlawfully enabled Endo/Teikoku to sell lidocaine patch 5% at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Lidoderm would have begun prior to September 15, 2013.

VII. INTERSTATE COMMERCE

101. At all material times, Endo/Teikoku manufactured, promoted, distributed, and sold substantial amounts of Lidoderm in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

102. At all material times, Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Lidoderm.

103. In furtherance of their efforts to monopolize and restrain competition in the market for lidocaine patch 5%, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

VIII. MONOPOLY POWER AND MARKET DEFINITION

104. At all relevant times, Endo/Teikoku had monopoly power over lidocaine patch 5% because it had the power to maintain lidocaine patch 5% prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lidoderm, with the exception of AB-rated generic versions of Lidoderm.

105. A small but significant, non-transitory price increase to Lidoderm by Endo/Teikoku would not have caused a significant loss of sales to other non-lidocaine patch 5% products.

106. Lidoderm does not exhibit significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of Lidoderm.

107. Because of, among other reasons, its use and varying ability to treat pain associated with post-herpetic neuralgia, Lidoderm is differentiated from all products other than AB-rated generic versions of Lidoderm.

108. Endo/Teikoku needed to control only Lidoderm and its AB-rated generic equivalents, and no other products, in order to maintain the price of Lidoderm profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Lidoderm would render Endo/Teikoku unable to profitably maintain its current prices of Lidoderm without losing substantial sales.

109. Endo/Teikoku also sold Lidoderm at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

110. Endo/Teikoku have had, and exercised, the power to exclude and restrict competition to Lidoderm and its AB-rated generics.

111. Endo/Teikoku's payment to Watson demonstrates that Endo/Teikoku enjoyed monopoly power with respect to lidocaine patch 5%.

112. Endo/Teikoku, at all relevant times, enjoyed high barriers to entry with respect to competition to the above-defined relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

113. To the extent that Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is lidocaine patch 5% (*i.e.*, Lidoderm and its AB-rated generic equivalents). During the

period relevant to this case, Endo/Teikoku has been able to profitably maintain the price of lidocaine patch 5% well above competitive levels.

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

115. At all relevant times, Endo/Teikoku's market share in the relevant market was 100%, implying a substantial amount of monopoly power.

**IX. EFFECTS ON COMPETITION, AND THE DAMAGES
CLAIMED IN THIS ACTION**

116. Watson's ANDA was approved August 23, 2012. Were it not for the unlawful Agreement alleged herein, Watson would have entered the market on or shortly after that date. In any event, one or more generic Lidoderm product would have entered the market well before the date provided in Defendants' unlawful Agreement, September 15, 2013.

117. But for the unlawful Agreement, an authorized generic version of Lidoderm would have been available on the market simultaneously with the launch of Watson's generic.

118. Defendants' unlawful Agreement has delayed generic competition and unlawfully enabled Endo/Teikoku to sell Lidoderm without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-rated generic versions of Lidoderm on August 23, 2012 or shortly thereafter, and in any event, earlier than September 15, 2013.

119. The generic manufacturers seeking to sell generic Lidoderm had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, manufacturing commercial launch quantities adequate to meet market demand, and, where appropriate, paying and receiving consideration for selective waiver and/or relinquishment of 180-day first-to-file marketing exclusivities.

120. Defendants' unlawful Agreement, which delayed introduction into the United States marketplace of generic versions of Lidoderm, has caused Plaintiff and the Class to pay more than they would have paid for lidocaine patch 5% absent Defendants' illegal conduct.

121. Typically, generic versions of brand drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, some or all of the direct purchases of branded drugs are rapidly substituted for generic versions of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand drug continues to lose even more sales to the generics.

122. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

123. But for Defendants' unlawful Agreement, direct purchasers, such as Plaintiff and members of the Class, would have paid less for lidocaine patch 5% by (a) substituting purchases of less-expensive AB-rated generic Lidoderm for their purchases of more-expensive branded Lidoderm, (b) receiving discounts on their remaining branded Lidoderm purchases, and/or (c) purchasing generic Lidoderm at lower prices sooner.

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

125. During the relevant period, Plaintiff and other members of the Class purchased substantial amounts of Lidoderm directly from Endo/Teikoku and purchased substantial amounts

of generic Lidoderm directly from Watson. As a result of Defendants' illegal conduct as alleged herein, Plaintiff and other members of the Class were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch 5% requirements. Plaintiff and the other Class members paid prices for lidocaine patch 5% that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower-priced generic Lidoderm instead of more expensive brand-name Lidoderm; and (2) Class members paid artificially inflated prices for lidocaine patch 5%.

126. 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.

X. CLAIMS FOR RELIEF

CLAIM I: VIOLATION OF 15 U.S.C. § 1 (AGREEMENT RESTRAINING TRADE)

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

128. In or about May 2012 and at times prior to the formal execution thereof Defendants entered into the Agreement, a continuing illegal contract, combination and conspiracy in restraint of trade under which Endo and Teikoku agreed to pay Watson substantial sums in exchange for Watson's agreement to delay bringing its generic version of Lidoderm to the market, the purpose and effect of which were to: (a) allocate 100% of the market for lidocaine patch 5% in the United States to Endo and Teikoku; (b) delay the availability of generic versions of Lidoderm in the United States, thereby protecting Lidoderm from any generic competition for over a year; (c) delay the entry of an authorized generic by Endo and Teikoku until 7.5 months after Watson's entry with

a generic Lidoderm product; and (d) fix, at supracompetitive levels, the price at which direct purchasers would pay for lidocaine patch 5%.

129. The Agreement harmed Plaintiff and the Class as set forth above.

130. Defendants are liable for the Agreement under a rule of reason standard.

131. There is and was no legitimate, nonpretextual, procompetitive justification for the payment from Endo and Teikoku to Watson that outweighs its harmful effect. Even if there were some conceivable such justification, the payment was not necessary to achieve such a purpose.

132. As a direct and proximate result of Defendants' 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)**

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

134. At all relevant times, Endo and Teikoku possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Endo and Teikoku possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

135. Through the Agreement alleged herein Endo/Teikoku and Watson conspired to maintain Endo and Teikoku's monopoly power in the relevant market in order to block and delay market entry of generic lidocaine patch 5%, *i.e.*, AB-rated generic versions of Lidoderm. The unlawful Agreement between Endo and Teikoku and Watson allocated all sales of lidocaine patch 5% in the United States to Endo and Teikoku; delayed the sales of generic Lidoderm products; and fixed the price at which Plaintiff and members of the Class would pay for lidocaine patch 5% at the higher, branded price.

136. The goal, purpose and/or effect of the Agreement was to maintain and extend Endo and Teikoku's monopoly power in the United States market for lidocaine patch 5% in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Agreement prevented and/or delayed generic competition to Lidoderm and enabled Endo and Teikoku to continue charging supracompetitive prices for Lidoderm without a substantial loss of sales.

137. Defendants knowingly and intentionally conspired to maintain and enhance Endo and Teikoku's monopoly power in the relevant market.

138. Defendants specifically intended that their Agreement would maintain Endo and Teikoku's monopoly power in the relevant market, and injured Plaintiff and the Class thereby.

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

140. The conspiracy harmed Plaintiff and the Class as set forth above.

141. There is and was no legitimate, nonpretextual procompetitive justification for Defendants' Agreement that outweighs its harmful effect. Even if there were some conceivable such justification, the Agreement is and was broader than necessary to achieve such a purpose.

142. As a direct and proximate result of Defendants' concerted conduct, as alleged herein, Plaintiff and the Class were harmed as aforesaid.

XI. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff, 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 the Plaintiff as the representative of the Class;

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

C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

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

XII. JURY DEMAND

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

Dated: December 11, 2013

By: **PRK 4859**

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