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10 **UNITED STATES DISTRICT COURT**  
11 **NORTHERN DISTRICT OF CALIFORNIA**

12  
13 **In re LIDODERM ANTITRUST**  
14 **LITIGATION**

Case No. 14-md-02521-WHO

15 THIS DOCUMENT RELATES TO:  
16 ALL DIRECT PURCHASER ACTIONS  
17

**DIRECT PURCHASER**  
**PLAINTIFFS' SECOND**  
**CONSOLIDATED AMENDED**  
**CLASS ACTION COMPLAINT**

18 DEMAND FOR JURY TRIAL  
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1 Plaintiffs Droguería Betances, Inc. (“Betances”), Rochester Drug Co-Operative,  
2 Inc. (“RDC”), American Sales Company, LLC (“ASC”), and Cesar Castillo, Inc.  
3 (“Castillo”) (collectively, “Plaintiffs”), bring this class action on behalf of themselves  
4 and all others similarly situated against defendants Endo Pharmaceuticals Inc.  
5 (“Endo”), Teikoku Pharma USA (“Teikoku Pharma”), Teikoku Seiyaku Co.  
6 (“Teikoku Seiyaku”) (collectively “Teikoku”), Watson Pharmaceuticals, Inc., and  
7 Actavis, plc, formerly known as Watson Pharmaceuticals, Inc., and Watson  
8 Laboratories, Inc. (collectively, “Watson”) (together with Endo and Teikoku, the  
9 “Defendants”) and allege as follows based on: (a) personal knowledge; (b) the  
10 investigation of their counsel; and (c) information and belief.

## 11 I. NATURE OF THE ACTION

12 1. This is a civil antitrust action brought by Plaintiffs on behalf of a class of  
13 direct purchasers of lidocaine patch 5%, sold by Endo under the brand name  
14 Lidoderm. Lidoderm is a lidocaine-containing patch for the treatment of pain  
15 associated with post-herpetic neuralgia. Plaintiffs seek overcharge damages arising  
16 out of Endo and Teikoku’s unlawful agreement with Watson not to compete in the  
17 market for lidocaine patch 5%.

18 2. On May 28, 2012, Endo and Teikoku entered into an unlawful non-  
19 competition agreement with Watson. Under the agreement (the “Reverse Payment  
20 Agreement” or “Agreement”), Watson agreed to delay marketing its less-expensive  
21 generic version of Lidoderm for almost 13 months, until September 15, 2013. In  
22 exchange, Endo and Teikoku agreed to pay Watson — and did, in fact, pay Watson —  
23 (a) at least \$96 million in the form of branded Lidoderm at no cost to Watson, which  
24 Watson could then resell (and did, in fact, resell) at that price; and (b) by forbearing  
25 from launching an authorized generic to compete with Watson’s generic Lidoderm  
26 until 7½ months after Watson’s generic belatedly entered the market, effectuating a  
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1 payment of hundreds of millions of dollars from Endo and Teikoku to Watson. In  
2 compliance with the Agreement, even though Watson was granted final FDA approval  
3 to launch its less-expensive generic Lidoderm patch on August 23, 2012, Watson did  
4 not come to market until September 15, 2013, thirteen (13) months later.

5 3. But for Defendants' unlawful Reverse Payment Agreement, one or more  
6 generic versions of Lidoderm would have entered the market as early as August 23,  
7 2012. Thus, absent Defendants' unlawful Reverse Payment Agreement, Plaintiffs and  
8 the members of the class would have been able to satisfy their lidocaine patch 5%  
9 requirements at significantly lower prices substantially earlier than they did, rather  
10 than being forced to pay for brand and generic Lidoderm at higher prices because of  
11 the unlawful agreement. Endo stated in its annual report that revenue from sales of  
12 Lidoderm was \$825 million in 2011 and \$947 million in 2012.

13 4. Defendants' unlawful Reverse Payment Agreement was designed to and did  
14 in fact: (i) delay and/or preclude the entry of less-expensive generic versions of  
15 lidocaine patch 5%; (ii) delay the introduction of an authorized generic lidocaine patch  
16 5%, which otherwise would have appeared on the market at a significantly earlier time  
17 and lowered prices further; (iii) fix, raise, maintain or stabilize the prices of lidocaine  
18 patch 5% products; (iv) permit Endo to maintain a monopoly for lidocaine patch 5%;  
19 (v) allocate 100% of the lidocaine patch 5% market in the United States, including its  
20 territories, possessions and the Commonwealth of Puerto Rico, to Endo for up to 13  
21 months; and (vi) allocate 100% of generic lidocaine patch 5% sales in the United  
22 States, including its territories, possessions and the Commonwealth of Puerto Rico, to  
23 Watson for 7½ months.

24 5. Defendants thus violated §§ 1 and 2 of the Sherman Act through their  
25 anticompetitive Reverse Payment Agreement, which unreasonably restrained  
26 competition in the market for lidocaine patch 5% and improperly maintained and  
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1 extended Endo's market and monopoly power by foreclosing or delaying competition  
2 from lower-priced generic versions of lidocaine patch 5%.

3 **II. JURISDICTION AND VENUE**

4 6. This action arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1  
5 and 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover  
6 threefold damages, costs of suit and reasonable attorneys' fees for the injuries  
7 sustained by Plaintiffs and members of the class (defined below) resulting from  
8 Defendants' unlawful restraint of trade and maintenance of market and monopoly  
9 power in the market for lidocaine patch 5% in the United States, including its  
10 territories, possessions and the Commonwealth of Puerto Rico. The Court has subject  
11 matter jurisdiction under 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. § 15.

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

17 **III. INTRADISTRICT ASSIGNMENT**

18 8. Assignment to this division in this District is proper because the interstate  
19 trade and commerce involved and affected by the violations of the antitrust laws was  
20 and is carried out within this division, and this action has been transferred to this  
21 division by the Judicial Panel on Multi-District Litigation.

22 **IV. PARTIES**

23 **A. Plaintiffs**

24 9. Betances is a corporation organized under the laws of the Commonwealth of  
25 Puerto Rico and located at Ave. Luis Munoz Marin Esq. El Troche Final, Caguas,  
26 Puerto Rico 00725. During the Class period (defined below), Betances purchased  
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1 branded Lidoderm directly from Endo, and purchased generic Lidoderm directly from  
2 Watson, and was injured as a result of Defendants' unlawful conduct.

3 10. RDC is a stock corporation duly formed and existing under the New York  
4 Cooperative Corporations Law, with its principal place of business located at 50 Jet  
5 View Drive, Rochester, New York 14624. During the Class period, RDC purchased  
6 branded Lidoderm directly from Endo, and purchased generic Lidoderm directly from  
7 Watson, and was injured as a result of Defendants' unlawful conduct.

8 11. ASC is a Delaware limited liability company with its principal place of  
9 business in Lancaster, Erie County, New York. ASC brings this action on its own  
10 behalf and as an assignee of McKesson Corporation. During the Class period, ASC  
11 purchased (a) branded Lidoderm directly from Anda Pharmaceuticals, Inc., a wholly-  
12 owned subsidiary of Watson; (b) branded Lidoderm from McKesson Corporation,  
13 which purchased directly from Endo; and (c) generic Lidoderm directly from Watson.  
14 ASC was injured as a result of Defendants' unlawful conduct.

15 12. Castillo is a corporation organized under the laws of the Commonwealth  
16 of Puerto Rico, with its principal place of business located at Bo. Quebradas Arena,  
17 Rd. #1 Km. 26.0, Río Piedras, Puerto Rico, 00926. During the Class period, Castillo  
18 purchased branded Lidoderm directly from Endo and was injured as a result of  
19 Defendants' unlawful conduct.

20 **B. Defendants**

21 13. Endo is a Delaware corporation, having its principal place of business at  
22 1400 Atwater Drive, Malvern, Pennsylvania, 19355. Endo markets and sells  
23 Lidoderm throughout the United States.

24 14. Teikoku Seiyaku is a company organized and existing under the laws of  
25 Japan, having its principal place of business in Higashikagawa, Kagawa, Japan.  
26 Teikoku Seiyaku is the owner, assignee or licensee of U.S. Patent No. 5,827,529 (the  
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1 “529 patent”) over which Endo and Teikoku sued Watson. Teikoku Seiyaku  
2 manufactures Lidoderm in Japan for commercial sale in the United States by Endo  
3 under a Manufacturing and Supply Agreement with Endo. Endo pays Teikoku  
4 Seiyaku royalties under that agreement. Teikoku Seiyaku does not sell Lidoderm to  
5 purchasers in the United States.

6 15. Teikoku Pharma is a California corporation, having its principal place of  
7 business at 1718 Ringwood Avenue, San Jose, California, 95131. Teikoku Pharma is  
8 a wholly-owned subsidiary of Teikoku Seiyaku, and is the holder of the New Drug  
9 Application for Lidoderm. Under the Manufacturing and Supply Agreement, Teikoku  
10 Pharma supplies Endo with the Lidoderm manufactured by Teikoku Seiyaku for  
11 commercial sale by Endo in the United States. Endo shared its monopoly profits with  
12 Teikoku Pharma by paying it royalties and certain per-unit acquisition costs under that  
13 agreement, as amended. Teikoku Pharma does not sell Lidoderm to purchasers in the  
14 United States.

15 16. Actavis, plc is incorporated under the laws of Ireland, having its  
16 principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland.  
17 Actavis, plc also has a place of business at Morris Corporate Center III, 400 Interpace  
18 Parkway, Parsippany, New Jersey, 07054.

19 17. Defendant Watson Pharmaceuticals, Inc. was a Nevada corporation,  
20 having its principal place of business at 311 Bonnie Circle, Corona, California, 92880.  
21 As a result of Watson Pharmaceuticals, Inc.’s acquisition of Actavis Group in or  
22 around October 2012, effective on or about January 24, 2013, Watson  
23 Pharmaceuticals, Inc. changed its name to Actavis, Inc. Actavis, Inc. changed its  
24 name to Actavis, plc on or about October 1, 2013.

25 18. Defendant Watson Laboratories, Inc. is a Nevada corporation, having its  
26 principal place of business at Morris Corporate Center III, 400 Interpace Parkway,  
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1 Parsippany, New Jersey 07054. Defendant Watson Laboratories, Inc. was a wholly-  
2 owned subsidiary of Watson Pharmaceuticals, Inc. and is now a subsidiary of Actavis,  
3 plc.

4 19. Watson was and is engaged in marketing, production and distribution of  
5 generic pharmaceutical products, including through its wholly-owned wholesaler  
6 affiliates including Anda, Inc., Anda Pharmaceuticals, Inc., and Valmed  
7 Pharmaceuticals, Inc.

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

15 21. With respect to all of the conduct complained of below, at all relevant  
16 times Endo acted in concert with Teikoku Pharma and Teikoku Seiyaku. Moreover,  
17 Endo, Teikoku Pharma, and Teikoku Seiyaku each signed the Reverse Payment  
18 Agreement with Watson. Furthermore, Endo, Teikoku Pharma, and Teikoku Seiyaku  
19 at all relevant times acted in concert with respect to the material provisions and  
20 performance of the Reverse Payment Agreement, which refers to Endo, Teikoku  
21 Pharma, and Teikoku Seiyaku collectively in provisions relating to the grant of patent  
22 licenses to Watson, the agreement not to launch a competing authorized generic for  
23 7½ months, and the obligation to deliver free brand Lidoderm product to pay Watson.  
24 On information and belief, Endo, Teikoku Pharma, and Teikoku Seiyaku are involved  
25 in a marketing enterprise that covers the distribution and marketing of Lidoderm in the  
26 United States.



1 **V. CLASS ACTION ALLEGATIONS**

2 22. Plaintiffs bring this action on behalf of themselves and, under Rule 23(a)  
3 and (b)(3) of the Federal Rules of Civil Procedure, as representatives of a Class  
4 defined as follows:

5 All persons or entities in the United States, including its territories,  
6 possessions, and the Commonwealth of Puerto Rico, who purchased brand  
7 or generic Lidoderm directly from any of the Defendants at any time  
8 during the period August 23, 2012 through the date on which the  
9 anticompetitive effects of Defendants' challenged conduct cease (the  
10 "Class").

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

13 23. Joinder of the members of the Class is impracticable. Plaintiffs believe  
14 the Class members are numerous and widely dispersed throughout the United States  
15 and its territories, possessions and the Commonwealth of Puerto Rico. Further, the  
16 Class is readily identifiable from information and records in the possession of  
17 Defendants. Direct notice to the members of the Class can be made upon obtaining  
18 the relevant information and records in the possession of Defendants.

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

24 25. Plaintiffs will fairly and adequately protect and represent the interests of  
25 the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the  
26 Class.



1           26. Plaintiffs are represented by counsel who are experienced and competent  
2 in the prosecution of class action antitrust litigation, and have particular experience  
3 with class action antitrust litigation in the pharmaceutical industry.

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

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

- 9           a. Whether the pay-for-delay conduct alleged herein constitutes a  
10 violation of the antitrust laws;
- 11           b. whether Defendants conspired to suppress generic competition to  
12 Lidoderm;
- 13           c. whether, pursuant to the Agreement, Watson agreed to, and did,  
14 delay its entry into the market with generic Lidoderm;
- 15           d. whether, pursuant to the Agreement, Endo and Teikoku made  
16 payments to Watson, and the amounts of each payment;
- 17           e. whether payments Endo and Teikoku made to Watson were for a  
18 purpose other than delaying Watson's entry into the market for  
19 lidocaine patch 5%;
- 20           f. whether there are legitimate procompetitive justifications  
21 explaining Endo and Teikoku's payments to Watson, such as being  
22 merely for avoided litigation costs or for services Watson was to  
23 perform for Endo and Teikoku;
- 24           g. whether Defendants' Agreement suppressed generic competition to  
25 Lidoderm;
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- 1 h. whether Defendants' Agreement harmed competition in the
- 2 lidocaine patch 5% market;
- 3 i. whether Defendants conspired or attempted to maintain Endo's
- 4 market and/or monopoly power in the lidocaine patch 5% market;
- 5 j. whether Endo possessed market and/or monopoly power in the
- 6 market for lidocaine patch 5%;
- 7 k. to the extent a relevant market or markets must be defined, what
- 8 that definition is or those definitions are;
- 9 l. whether the activities of Defendants as alleged herein have
- 10 substantially affected interstate commerce;
- 11 m. whether, and to what extent, Defendants' challenged conduct
- 12 caused antitrust injury to the business or property of Plaintiffs and
- 13 the members of the Class in the nature of overcharges; and
- 14 n. the quantum of overcharges paid by the Class in the aggregate.

15 29. Class action treatment is a superior method for the fair and efficient  
16 adjudication of the controversy because, in addition to other benefits, such treatment  
17 will permit a large number of similarly situated persons to prosecute their claims in a  
18 single forum simultaneously, efficiently, and without the unnecessary duplication of  
19 evidence, effort, and expense that numerous individual actions would engender. The  
20 benefits of proceeding through the class mechanism, including providing injured  
21 persons or entities with a method for obtaining overcharge damages for claims that  
22 might not be practicable to pursue individually, substantially outweigh any difficulties  
23 that may arise in management of this class action.

24 30. Plaintiffs know of no difficulty to be encountered in the maintenance of  
25 this action as a class action that would preclude its maintenance as a class action.  
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1 **VI. REGULATORY BACKGROUND**

2 **A. The Regulatory Structure for Approval of Generic Drugs**

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

8 32. When FDA approves a brand manufacturer’s NDA, the brand  
9 manufacturer may list in the FDA’s book of Approved Drug Products with  
10 Therapeutic Equivalence Evaluations (called the “Orange Book”) any patent that  
11 claims either the approved drug or approved methods of use of the drug and could  
12 reasonably be asserted against a generic manufacturer who makes, uses, or sells a  
13 generic version of the brand drug prior to the expiration of the listed patent(s). Patents  
14 issued after NDA approval may be listed in the Orange Book within 30 days of  
15 issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

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

20 **1. The Hatch-Waxman Amendments**

21 34. The Hatch-Waxman Amendments, enacted in 1984, simplified the  
22 regulatory hurdles for prospective generic manufacturers by eliminating the need for  
23 them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a  
24 generic version of a brand drug may instead file an Abbreviated New Drug  
25 Application (“ANDA”). An ANDA relies on the scientific findings of safety and  
26 effectiveness included in the brand manufacturer’s NDA, and must show that the  
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1 generic drug contains the same active ingredient(s), dosage form, route of  
2 administration, and strength as the brand drug, and is absorbed at the same rate and to  
3 the same extent as the brand drug — that is, that the generic drug is both  
4 pharmaceutically equivalent and bioequivalent (together, “therapeutically equivalent”)  
5 to the brand drug. *See generally* 21 U.S.C. §355(j) *et seq.*

6 35. The FDCA and Hatch-Waxman Amendments operate on the principle  
7 that bioequivalent drug products containing identical amounts of the same active  
8 ingredients, having the same route of administration and dosage form, and meeting  
9 applicable standards of strength, quality, purity and identity, are therapeutically  
10 equivalent and may be substituted for one another. Bioequivalence demonstrates that  
11 the active ingredient of the proposed generic drug is absorbed at the site of drug action  
12 to the same extent and for the same amount of time as the brand counterpart. 21  
13 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in  
14 dosage form, safety, strength, route of administration, and intended use.

15 36. Generic drugs that are therapeutically equivalent to their brand  
16 counterparts are given an “AB” rating by FDA, allowing their substitution for the  
17 brand when a prescription for the brand is presented at the pharmacy.

18 37. Congress enacted the Hatch-Waxman Amendments to expedite the entry  
19 of generic competitors, thereby reducing healthcare expenses nationwide. Congress  
20 also sought to protect pharmaceutical companies’ financial incentives to create new  
21 and innovative products.

22 38. The Hatch-Waxman Amendments achieved both goals, advancing  
23 substantially the rate of generic product launches, and ushering in an era of historic  
24 revenues for brand name pharmaceutical companies. In 1983, before the Hatch-  
25 Waxman Amendments, only 35% of the top-selling drugs with expired patents had  
26 generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for  
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1 brand and generic drugs totaled \$21.6 billion, with generic drugs accounting for 18.6%  
2 of total prescriptions. By 2013, total prescription drug revenue had climbed to more  
3 than \$329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS  
4 INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF  
5 HEALTHCARE, at 30, 51 (Apr. 2014), *available at*  
6 [http://www.imshealth.com/cds/imshealth/Global/Content/  
7 Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI\\_US\\_Use\\_of\\_Meds\\_for\\_2  
8 013.pdf](http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf) (last accessed June 2, 2014).

9 **2. Paragraph IV Certifications**

10 39. To obtain FDA approval of an ANDA, a generic manufacturer must  
11 certify that the generic drug addressed in its ANDA will not infringe any patents listed  
12 in the Orange Book as claimed by the brand drug. Under the Hatch-Waxman  
13 Amendments, a generic manufacturer's ANDA must contain one of four certifications:

- 14 a. that no patent for the brand drug has been filed with the FDA (a  
15 "Paragraph I certification");  
16 b. that the patent for the brand drug has expired (a "Paragraph II  
17 certification");  
18 c. that the patent for the brand drug will expire on a particular date and the  
19 generic company does not seek to market its generic product before that  
20 date (a "Paragraph III certification"); or  
21 d. that the patent for the brand drug is invalid or will not be infringed by the  
22 generic manufacturer's proposed product (a "Paragraph IV certification").

23 40. If a generic manufacturer files a Paragraph IV certification that the listed  
24 patent is invalid or will not be infringed, it must promptly give notice to the brand  
25 manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a  
26 cause of action for patent infringement regardless of the merits of such an action. If  
27

1 the brand manufacturer initiates a patent infringement action against the generic filer  
2 within forty-five days of receiving notification of the Paragraph IV certification  
3 (“Paragraph IV Litigation”), FDA will not grant final approval to the ANDA until the  
4 earlier of (a) the passage of thirty months (the “30-month stay”), or (b) the issuance of  
5 a decision by a court that the patent is invalid or not infringed by the generic  
6 manufacturer’s ANDA. Until one of those conditions occurs, FDA may grant  
7 “tentative approval,” but cannot grant final approval to authorize the generic  
8 manufacturer to go to market with its product. Accordingly, the timely filing of an  
9 infringement action provides the patent owner with the equivalent of an automatic  
10 preliminary injunction preventing final FDA approval of the challenged ANDA for up  
11 to 30 months, even if there is no merit to the infringement action.

12 41. As an incentive to spur generic companies to seek approval of generic  
13 alternatives to brand drugs, the first generic manufacturer to file an ANDA containing  
14 a Paragraph IV certification typically gets a period of protection from competition  
15 from other generic versions of the drug. The first generic applicant often receives 180  
16 days of market exclusivity, meaning that FDA will not approve any other ANDA for  
17 that same generic drug for at least six months. This allows the first filer to be free  
18 from competition from other generic companies for at least six months. However, the  
19 brand company is free to (and often does) launch its own “authorized generic” during  
20 the 180 day exclusivity period.

21 **B. Generic Versions of Brand Drugs are Significantly Less Expensive than**  
22 **Their Corresponding Brand Versions.**

23 42. Typically, AB-rated generics are priced significantly below their brand  
24 counterparts. “Although generic drugs are chemically identical to their branded  
25 counterparts, they are typically sold at substantial discounts from the branded price.  
26 According to the Congressional Budget Office, generic drugs save consumers an  
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1 estimated \$8 to \$10 billion a year at retail pharmacies. Even more billions are saved  
2 when hospitals use generics.” See <http://www.fda.gov/Drugs/>  
3 [ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDr](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm)  
4 [ugs/ucm144456.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm).

5 **1. Generic Versions of Brand Drugs Quickly and Predictably Take**  
6 **Sales from Their Corresponding Brand Versions**

7 43. In every state, pharmacists are permitted (and in some states, required) to  
8 substitute a generically-equivalent product for the brand product prescribed, unless the  
9 doctor has indicated that the prescription for the brand product must be “dispensed as  
10 written.” Because of the significant savings they allow and other institutional features  
11 of the pharmaceutical industry, generic versions are substituted by pharmacists who  
12 are presented with a prescription for the brand counterpart immediately upon launch of  
13 the generic.

14 44. As more generic sellers enter the market, prices for generic versions of a  
15 drug predictably decrease even further because of competition among the generic  
16 sellers. Pharmacy substitution, and thus the loss of sales volume by the brand drug to  
17 the corresponding generic, thereby accelerates. According to a recent FTC staff study,  
18 within one year of generic entry, 90% of prescriptions are filled with the brand’s  
19 generic substitute, and at prices that “are, on average, 85% lower than the pre-entry  
20 branded drug price.” *“Pay for Delay: How Drug Company Pay-Offs Cost Consumers*  
21 *Billions,”* FTC Staff, January 2010 at 8.

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

25 46. Until a generic manufacturer enters the market, there is no generic drug to  
26 substitute for and otherwise compete with the brand drug, thereby allowing the brand  
27 manufacturer to continue to charge supracompetitive prices profitably, without losing



1 a substantial portion of its brand sales. Consequently, brand manufacturers have a  
2 strong incentive to delay the introduction of generic competition into the market,  
3 including paying generic companies to delay launching their generic products, such as  
4 in this case. For Endo and Teikoku, that incentive was particularly strong: in 2012,  
5 Lidoderm accounted for 31% of Endo's revenues and resulted in payments of  
6 approximately \$235 million from Endo to Teikoku.

7 **2. No-Authorized-Generic Promises Are a Means By Which Brand**  
8 **Companies Pay Generic Companies to Delay Generic Competition**

9 47. One mechanism employed by brand companies to thwart generic  
10 competition is to make a payment to a first-filing generic company in the form of the  
11 brand company's promise not to launch an "authorized generic" version of the brand  
12 drug during the first 180 days of generic marketing (and sometimes longer). An  
13 authorized generic is the brand drug, manufactured just like the brand product, but  
14 sold as a generic product under the same approval as the brand product's original  
15 NDA. Because the brand manufacturer already has approval to sell its brand drug, it  
16 does not need to file an ANDA, or obtain any additional approval, to market an  
17 identical generic version of its own brand drug. ANDA filers have no patents on, and  
18 no right to be free from, an authorized generic version of the brand drug.

19 48. For the brand company, an authorized generic launched during the first  
20 180 days of generic marketing (or longer) provides a low cost, low risk means to  
21 regain some of the revenue lost from the termination of brand exclusivity. For the  
22 generic manufacturer enjoying exclusivity as the first generic to be marketed,  
23 however, an authorized generic launch has a huge negative impact on its revenue. A  
24 generic company generally earns about 80% of its total income from a given generic  
25 product during the period that it is the sole generic on the market. An authorized  
26 generic, when launched during that time, is typically priced competitively as against  
27 the other generics, and will capture 50% or more of total generic sales during that

1 period. A brand's promise not to launch an authorized generic during the initial period  
2 of generic marketing is thus a very valuable payment to the generic company that is  
3 the first-filer generic entrant. It doubles the first-filer generic entrant's sales volume  
4 during that time, and, because it removes a source of price competition from the  
5 market, it more than doubles the first-filer generic entrant's revenues and profits.  
6 Correspondingly, a brand's promise not to launch an authorized generic represents a  
7 substantial sacrifice of the revenues and profits that the authorized generic would  
8 otherwise have created for the brand. Those revenues and profits are instead ceded, by  
9 way of the no-authorized-generic promise, to the generic company.

10 49. In a report by the Federal Trade Commission ("FTC") issued at the  
11 request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects*  
12 *and Long-Term Impact* ("Authorized Generic Drugs"), the FTC concluded that no-  
13 authorized-generic promises are being used as a payment by brands to generics for  
14 delayed generic entry. The FTC analyzed documents and empirical data covering  
15 more than 100 companies and found that the presence of authorized generic  
16 competition reduces the first-filer generic's revenues by more than 50% during the  
17 first 180 days of generic marketing. *Authorized Generic Drugs* at iii, vi, 41-48, 57-59,  
18 available at [http://www.ftc.gov/sites/default/files/documents/reports/authorized-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
19 [generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
20 [commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf)  
21 [report-federal-trade-commission.pdf](http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf).

22 50. The FTC found that a generic company makes significantly less money  
23 when it competes with an authorized generic because (1) the authorized generic takes  
24 a significant share of generic sales away from the first-filer (around 50%), and (2)  
25 wholesale and retail prices decrease when the first-filer faces an authorized generic  
26 due to competition between the two. Both of these factors reduce the generic  
27

1 company's sales and revenues. With a no-authorized-generic promise, the generic  
2 company avoids this reduction in revenue. The FTC noted that "there is strong  
3 evidence that agreements not to compete with an authorized generic have become a  
4 way for brand-name companies to compensate generic competitors for delaying entry.  
5 These agreements can be part of 'pay-for-delay' patent settlements, which have long  
6 concerned the Commission." *See id.* at vi.

7 51. A 2006 study sponsored by the brand drug company trade association,  
8 PhRMA, similarly found that competition from an authorized generic results in lower  
9 generic prices.

10 52. An agreement between a brand and generic drug company — horizontal  
11 competitors — that the brand company will withhold an authorized generic from the  
12 market in exchange for the generic company's agreement to delay market entry with  
13 its generic version of the brand drug, injures consumers twice over: first, by  
14 prolonging the period during which only the high-priced brand is available, and  
15 second, by ensuring that, once delayed generic competition begins, generic prices are  
16 artificially inflated because of the absence of the authorized generic.

17 53. For a first-filer generic like Watson, of a brand product like Lidoderm,  
18 the difference between (1) selling the only generic product and (2) selling a generic  
19 product while competing against an authorized generic, for the first months of generic  
20 marketing, constitutes a very large payment — reaching hundreds of millions of  
21 dollars. These economic realities are well known in the pharmaceutical industry, and  
22 the FTC's authorized generic report cites numerous documents from industry  
23 participants confirming the financial impact of an authorized generic and, by  
24 necessary implication, its absence.

25 54. No-authorized-generic promises like the one Endo and Teikoku made as  
26 payment in exchange for Watson's promise to delay introduction of generic Lidoderm  
27

1 thus allow horizontal competitors to benefit from an agreement not to compete and  
2 deny purchasers the consumer surplus that should flow to them from increased  
3 competition.

## 4 **VII. FACTUAL ALLEGATIONS**

### 5 **A. Background**

#### 6 **1. Approval of Brand Lidoderm and its Purported Patent Protection**

7 55. Lidoderm is a prescription lidocaine-containing patch approved to treat  
8 pain associated with post-herpetic neuralgia. The active ingredient in Lidoderm is 5%  
9 lidocaine. While other drugs are available to treat the same or similar medical  
10 conditions, they are not AB-rated to Lidoderm, cannot be automatically substituted for  
11 Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand  
12 with respect to Lidoderm, and are not economic substitutes for, nor reasonably  
13 interchangeable with, Lidoderm.

#### 14 **a. Initial Approval of Lidoderm**

15 56. On March 19, 1999, FDA approved NDA 200612, submitted by Hind  
16 Health Care, Inc. (“Hind”), which sought to market an adhesive patch containing 5%  
17 lidocaine under the brand name Lidoderm. Lidoderm was awarded Orphan Drug  
18 Exclusivity by FDA, meaning that no generic competitor could get FDA approval to  
19 market a generic Lidoderm product until March 2006.

20 57. In 1998, Hind granted to Endo the exclusive right to market and  
21 distribute Lidoderm in the United States. Hind subsequently transferred full  
22 ownership of and responsibility for the Lidoderm NDA to Teikoku, effective June 1,  
23 1999. Teikoku then granted Endo the exclusive right to market and distribute the  
24 Lidoderm patch in the United States under Teikoku’s NDA, and Endo launched  
25 Lidoderm in the United States in 1999.

1 **b. Endo and Teikoku's Acquisition of Lidoderm Patents**

2 58. Endo and Teikoku owned or obtained assignments of or licenses to a  
3 number of patents associated with Lidoderm. Subsequently, Teikoku listed several  
4 patents in the Orange Book as covering Lidoderm. As of January 2010 (after Watson  
5 had filed ANDA No. 200675, the first ANDA filed as to Lidoderm), Teikoku had  
6 three patents listed in the Orange Book. By agreement with Teikoku, Endo had the  
7 sole and exclusive right to institute, prosecute, and control any lawsuits alleging  
8 infringement of any Orange Book-listed patents covering Lidoderm, and Teikoku was  
9 required to assign any such infringement claims to Endo.

10 59. The first was U.S. Patent No. 5,411,738 (the "'738 patent"), which is a  
11 method of use patent for treating certain types of pain with lidocaine using a topical  
12 delivery mechanism and a gel formulation of lidocaine. The second was U.S. Patent  
13 No. 5,601,838 ("the '838 patent"), which is a method of use patent for treating certain  
14 types of pain with lidocaine. The '738 and '838 patents both were assigned to Hind,  
15 both expired on May 2, 2012, and are referred to collectively as the "Hind patents."

16 60. The third patent that Teikoku listed in the Orange Book as covering  
17 Lidoderm was U.S. Patent No. 5,827,529 (the "'529 patent"), which is a formulation  
18 patent for a lidocaine patch. This patent was assigned to Teikoku, and is set to expire  
19 on October 17, 2015. Endo is the exclusive licensee of the '529 patent.

20 61. The '529 patent, titled "External Preparation for Application to the Skin  
21 Containing Lidocaine," issued on October 27, 1998, from an application filed on June  
22 10, 1994. That application was a continuation of an application filed on March 30,  
23 1992.

24 62. The '529 patent claims foreign priority to Japanese Application No. 3-  
25 067353, filed March 30, 1991.

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

4           64. Claim 1 of the '529 patent claims a patch comprising “a drug-retaining  
5 layer placed on a support,” in which the drug-retaining layer comprises an “adhesive  
6 gel base and 1 to 10% by weight of lidocaine.” The claimed “adhesive gel base”  
7 consists of three components within specific percentage weight ranges: (i) “0.5 to  
8 50% by weight of a water-soluble high molecular weight substance”; (ii) “30 to 70%  
9 by weight of water”; and (iii) “1 to 70% by weight of a water-retaining agent.”

10                   **c. Endo and Teikoku Seek to Bolster Lidoderm’s Patent**  
11                   **Coverage**

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

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

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

25           68. In or about November 2010, Teikoku submitted the '510 patent to FDA  
26 for listing in the Orange Book with respect to Lidoderm.  
27

1           69. As of January 2011, Endo and Teikoku had four patents listed in the  
2 Orange Book related to Lidoderm: the two Hind patents (which expired in May  
3 2012), the '529 patent, and the '510 patent.

4           70. In or about May 2011, in exchange for \$2 million, Endo acquired from  
5 LecTec full title to the '263 patent, the '510 patent and three other patents. The three  
6 other patents were U.S. Patent No. 6,096,333 (the "'333 patent"), (ii) U.S. Patent No.  
7 6,096,334 (the "'334 patent"); and (iii) U.S. Patent No. 6,361,790 (the "'790 patent")  
8 (collectively with the '263 and the '510 patents, "the Rolf patents," named for one of  
9 the inventors). These three patents all cover methods of formulating a medicinal  
10 adhesive patch and expired on March 30, 2014. Other than the '510 patent, none of  
11 the Rolf patents was listed in the Orange Book with respect to Lidoderm.

## 12           **2. Watson's ANDA Threatens Endo and Teikoku's Weak Patents**

13           71. On November 13, 2009, Watson submitted ANDA No. 200675 to FDA,  
14 seeking to market a generic version of Lidoderm. On or about January 14, 2010,  
15 Watson notified Teikoku of its November 13, 2009 ANDA filing.

16           72. Watson's notice letter included a Paragraph IV certification that the  
17 commercial manufacture, use and/or sale of its generic Lidoderm product would not  
18 infringe any claim of the '529 patent, and/or that the '529 patent was invalid and/or  
19 unenforceable. Watson was the first generic manufacturer to file an ANDA with a  
20 Paragraph IV certification with respect to Lidoderm, potentially entitling it to a six-  
21 month exclusivity period, free from competition from any other ANDA-filing generic  
22 company. This exclusivity, however, would not have protected Watson from  
23 competition from an authorized generic version of Lidoderm.

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



1           74.    Watson made no certification to any of the Rolf patents because the Rolf  
2 patents were not listed in the Orange Book until November 2010, a year after Watson  
3 filed its ANDA.

4           75.    FDA granted final approval to Watson's ANDA on August 23, 2012, but  
5 Watson did not launch its approved generic Lidoderm product until September 16,  
6 2013, because of the unlawful Reverse Payment Agreement with Endo and Teikoku.  
7 No patents asserted, or capable of being asserted, by Endo and Teikoku would or  
8 could have prevented Watson from launching its approved generic Lidoderm product.

### 9           **3.       Endo and Teikoku Scramble to Protect Their Franchise**

10          76.    On February 19, 2010, Endo and Teikoku sued Watson in the United  
11 States District Court for the District of Delaware (*Endo Pharm. Inc., et al., v. Watson*  
12 *Labs., Inc.*, Civil Action No. 10-cv-00138-GMS), alleging that Watson's generic  
13 Lidoderm infringed the '529 patent (the "'529 Litigation"). As a result of the filing of  
14 the '529 Litigation, a 30-month Hatch-Waxman stay of FDA approval applied to  
15 Watson's ANDA, which precluded FDA from approving Watson's ANDA until (i)  
16 that stay expired in mid-July of 2012, or (ii) entry of a final judgment that the '529  
17 patent was invalid, unenforceable, and/or not infringed.

18          77.    Watson raised numerous defenses, including that the '529 patent was  
19 invalid and/or unenforceable.

20          78.    As the '529 Litigation moved toward trial, Endo filed yet another suit  
21 against Watson, this time using the Rolf patents. On or about June 29, 2011, Endo  
22 filed suit against Watson in the United States District Court for the District of  
23 Delaware (*Endo Pharm. Inc. v. Watson Labs., Inc.*, Civil Action No. 11-cv-00575-  
24 GMS) (the "Rolf Patent Litigation"), alleging that Watson's generic Lidoderm product  
25 would infringe three of the Rolf patents – the '333 patent, the '334 patent, and the  
26 '510 patent. Only the '510 patent had been listed in the Orange Book. Because the  
27

1 Rolf patents had not been listed in the Orange Book when Watson filed its ANDA, the  
2 Rolf Patent litigation did not result in a 30-month Hatch-Waxman stay.

3 **a. The '529 Litigation Exposed the Weakness of Endo and**  
4 **Teikoku's '529 Patent**

5 79. After the June 27, 2011 *Markman* hearing in the '529 Litigation, Judge  
6 Sleet rejected Endo's claim construction position, strengthening Watson's defense to  
7 Endo and Teikoku's infringement claims. The '529 Litigation then proceeded to a  
8 bench trial in February 2012, in which Watson presented evidence of the invalidity of  
9 the '529 patent, as well as evidence that Watson's generic did not infringe the patent.  
10 The evidence at trial was overwhelmingly in favor of Watson, exposing the '529  
11 patent to a determination that it was invalid or unenforceable and that the patent did  
12 not cover either the brand product or Watson's generic product.

13 **(1) The '529 Patent Was Invalid**

14 80. The evidence developed during the '529 Litigation revealed that the same  
15 hydrogel transdermal patch technology claimed in the '529 patent had previously been  
16 disclosed in multiple pieces of prior art that were not disclosed to the patent examiner,  
17 but were well known to Endo and/or Teikoku (the "Teikoku Prior Art"). Each of the  
18 pieces of Teikoku Prior Art discloses a hydrogel transdermal patch formulation  
19 substantially similar to that claimed in the '529 patent.

20 81. Each piece of the Teikoku Prior Art discloses an "adhesive gel base"  
21 consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a  
22 water-retaining agent, all of which fall within the percentage ranges claimed in the  
23 '529 patent. Each shares at least one inventor with the '529 patent, and also shares the  
24 same applicant, prosecuting attorneys, or assignee with the '529 patent.

25 82. During the prosecution of the '529 patent, the PTO rejected the patent  
26 four times, noting that because lidocaine was conventionally used in transdermal  
27 patches, it would have been obvious to place lidocaine into available prior art patches.

1 The applicants consistently distinguished other prior art patches cited by the  
2 Examiner, arguing that the patch in the '529 patent was "unique." The applicants  
3 never disclosed the Teikoku Prior Art to the PTO, or a prior art patent with the same  
4 elements as the '529 patent, which would have showed that the patch technology in  
5 the '529 patent was not unique, and in fact had been previously patented. The PTO  
6 never cited the Teikoku Prior Art.

7 83. Each of these prior art references is prior art to the '529 patent because  
8 each was publicly available and accessible more than one year before the March 30,  
9 1991 priority date of the '529 patent. Each of the prior art references predates the  
10 priority date of the '529 patent by over a year, and thus invalidates the '529 patent.  
11 The '529 patent was not capable of preventing Watson from launching its approved  
12 generic Lidoderm product.

### 13 (2) The '529 Patent Was Not Infringed

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

24 85. In the '529 patent, the first Markush group related to "a water-soluble  
25 high molecular weight substance selected from the group consisting of gelatin, starch,  
26 agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin,  
27

1 methylcellulose, methylcellulose sodium, carboxymethylcellulose,  
2 carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl pyrrolidone, copolymer  
3 of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and  
4 locust bean gum.”

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

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

14 88. Watson’s generic Lidoderm product contained at least *four* water-soluble  
15 high-molecular-weight substances, and *three* water-retaining agents. (So does  
16 Lidoderm.) Thus, it did not infringe the ’529 patent because it contained more than  
17 one substance from each Markush group. As a result, Watson’s generic Lidoderm  
18 product did not infringe the ’529 patent. The ’529 patent was not capable of  
19 preventing Watson from launching its approved generic Lidoderm product.

20 **b. The Rolf Patent Litigation**

21 89. The Rolf patents afforded Endo and Teikoku no basis to prevent Watson  
22 from launching its approved generic Lidoderm product, either. Endo sued Watson  
23 only on some of the Rolf patents (the ’510, ’333, and ’334 patents). Watson had  
24 raised defenses and counterclaims alleging those patents were invalid and/or  
25 unenforceable and that its product did not infringe them. Endo and Teikoku did not  
26 even bother to sue Watson on the ’263 patent. The Rolf Patent Litigation barely  
27

1 proceeded past the pleading stage. The Rolf patents posed no reasonable risk to  
2 Watson of patent infringement liability.

3 90. Of the Rolf patents, only the '510 patent had been asserted by its previous  
4 owner, LecTec, against Endo with respect to its Lidoderm product in the LecTec  
5 Litigation in 2008. As Endo and Teikoku learned from the LecTec Litigation, the  
6 '510 patent was subject to a strong invalidity challenge. The '510 patent was invalid  
7 as obvious in view of prior art references that were not submitted to the PTO during  
8 the prosecution of the '510 patent. Watson, too, was aware of the infirmities of the  
9 '510 patent from the publicly filed pleadings in the LecTec Litigation. The '510  
10 patent was incapable of preventing Watson from launching its approved generic  
11 Lidoderm product.

12 91. The '333 and '334 patents were also not infringed by Watson. Indeed,  
13 during the LecTec litigation, LecTec had not even sued Endo for infringement of the  
14 '333 and '334 patents with respect to Lidoderm. When Endo ultimately settled the  
15 LecTec Litigation in November 2009, it obtained licenses only to the '263 and '510  
16 patents, further demonstrating that licenses to the '333 and '334 patents were  
17 irrelevant to the use, manufacture, or sale of Lidoderm. Watson's generic patch, a  
18 copy of the Endo patch, similarly would not infringe the '333 and '334 patents.

19 92. Indeed, Endo did not bother to obtain the rights to the '333 and '334  
20 patents until May 2011, when it bought the rights to all of the Rolf patents from  
21 LecTec for just \$2 million, still further evidence that those patents were incapable of  
22 preventing Watson from launching its approved generic Lidoderm product. None of  
23 the Rolf patents was capable of preventing Watson from launching its approved  
24 generic Lidoderm product.

1 **B. Endo and Teikoku Enter the Unlawful Reverse Payment Agreement with**  
2 **Watson**

3 93. On or about May 28, 2012 — after the February 2012 bench trial and as  
4 Endo, Teikoku and Watson were awaiting a decision from Judge Sleet — Endo and  
5 Teikoku entered into an agreement with Watson ending the patent litigation related to  
6 Lidoderm. The Reverse Payment Agreement ended the '529 Litigation and the Rolf  
7 Patent Litigation, and obviated the need for Judge Sleet to render decisions on the  
8 validity, enforceability, and infringement of the patents Endo and Teikoku had  
9 asserted against Watson.

10 94. Under the Agreement, Watson agreed to delay launching its generic  
11 Lidoderm product until a “Start Date” of September 15, 2013 unless before that date  
12 another generic product launched (a virtual impossibility) or Watson faced forfeiture  
13 of its 180-day exclusivity for failing to go to market (also a virtual impossibility). The  
14 Agreement specifically provides:

15 Subject to Section 2(d), Watson agrees, on behalf of itself and its  
16 Affiliates, that, prior to the Start Date, it and its Affiliates shall not  
17 directly or indirectly market, offer to sell, sell, have sold, import,  
18 manufacture or have manufactured in the Territory any of Watson’s  
19 Generic Product. Watson acknowledges and agrees that each of Endo and  
20 Teikoku would be irreparably harmed should Watson breach this Section  
21 2(e). Nothing in this Agreement shall prohibit or preclude Watson from  
22 exercising its rights under 35 U.S.C. § 271(e)(1). [Settlement Agreement  
23 at Section 2(e).]

24 \*\*\*

25 “Start Date” means the earliest of: (i) September 15, 2013; (ii) the date of  
26 Launch of any Generic Product other than Watson’s Generic Product; or  
27 (iii) the last day before Watson would forfeit its 180-day generic drug  
28 exclusivity with respect to Watson's Generic Product due to the operation  
of 21 U.S.C. 355(j)(5)(D)(ii) as a result of a forfeiture event under 21  
U.S.C. 355(j)(5)(D)(i)(I). [*Id.* at Section 1(v).]



1           95. As one *quid pro quo* for Watson's promise to delay entry of its generic  
 2 Lidoderm product until September 15, 2013, Endo and Teikoku promised to share  
 3 with Watson the monopoly profits Endo would reap (and share with Teikoku) from  
 4 Lidoderm's extended market exclusivity by paying Watson at least \$96 million (in the  
 5 form of brand Lidoderm provided by Endo and/or Teikoku at no cost to Watson) at the  
 6 rate of \$12 million per month from January 1, 2013 through August 1, 2013. Watson  
 7 was free to sell the brand Lidoderm product and retain the full proceeds of those sales.  
 8 This payment was no different than if Endo had made those sales itself and then Endo  
 9 and Teikoku paid Watson their respective portions of the \$96 million in cash. The  
 10 Agreement specifically provides:

11           Endo/Teikoku shall provide, at no cost, to Watson's Wholesaler Affiliate  
 12           Brand Product of value totaling twelve million dollars (\$12,000,000) per  
 13           month, as measured at the time of each delivery by the then-prevailing  
 14           Wholesale Acquisition Cost as defined in the Red Book or, if the Red  
 15           Book is not available, any other comparable U.S. price listing ("WAC"),  
 16           on the first business day of each month beginning January 1, 2013 and  
 17           ending August 1, 2013 (for a total of eight (8) months) for Watson's  
 18           Wholesaler Affiliate's disposal as provided in Section 3(e). Endo shall  
 19           provide to Watson's Wholesaler Affiliate an invoice with respect to such  
 20           Brand Product, which invoice shall reflect the transfer of Brand Product  
 21           to Watson's Wholesaler Affiliate at no cost. Notwithstanding the  
 22           foregoing, Endo/Teikoku's obligations under this Section 3(b) shall  
 23           terminate immediately upon the Launch of any Third Party Generic  
 24           Product in the Territory. The Brand Product provided to Watson's  
 25           Wholesaler Affiliate by Endo/Teikoku shall have the same NDC number  
 26           as the Brand Product sold by Endo. In any month in which Endo/Teikoku  
 27           has provided to Watson's Wholesaler Affiliate any Brand Product under  
 28           this Section 3(b), and in which a Third Party has Launched a Generic  
 Product in the Territory, Watson shall either (i) return to Endo a pro rata  
 quantity of the Brand Product delivered by Endo/Teikoku during such  
 month, or (ii) reimburse Endo in cash for the value of the Brand Product  
 (based on the WAC measured at the time of delivery by Endo/Teikoku to  
 Watson's Wholesaler Affiliate), in either case for the pro rata portion of  
 the month on and after such Launch[.] \* \* \* Such return or  
 reimbursement shall be made by Watson to Endo within five (5) business  
 days of the date of the Launch of a Generic Product in the Territory.  
 [Settlement Agreement at Section 3(b) (emphasis added).]

\*\*\*

The Brand Product supplied by Endo/Teikoku to Watson's Wholesaler  
 Affiliate under Sections 3(b) through (d) may be resold solely by  
 Watson's Wholesaler Affiliate to Third Parties for use solely in the

- 28 -



1 Territory on pricing and other terms determined by Watson's Wholesaler  
2 Affiliate in its sole discretion, provided that neither Watson nor any of its  
3 Affiliates (including its Wholesaler Affiliate) shall sell, distribute or  
4 dispose of Branded Product in any manner that would constitute a  
5 Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all  
6 Endo price-related contracts as communicated to all Endo wholesalers  
7 from time to time in the ordinary course of business, provided that the  
8 price related contracts do not impose any requirements on Watson's  
9 Wholesaler Affiliate that would be inconsistent with requirements  
10 imposed upon other Lidoderm® wholesalers, and further provided that  
11 such price-related contracts shall not conflict with the terms of this  
12 Agreement. Watson shall comply with all Applicable Laws in connection  
13 with its resale of the Brand Product. [Settlement Agreement at Section  
14 3(e).]

96. Endo and Teikoku also agreed to make additional payments to Watson if  
15 Watson did not receive FDA approval for its generic Lidoderm product by January 1,  
16 2014, as well as additional payments if Watson did not receive approval by January 1,  
17 2015. Neither situation came to pass or was expected to come to pass: Watson  
18 received final FDA approval on August 23, 2012, within three (3) months of  
19 Defendants' execution of the Reverse Payment Agreement.

97. As the Agreement expressly provided, this \$96 million payment from  
20 Endo and/or Teikoku to Watson was expressly to induce Watson to quit its challenge  
21 to Endo and Teikoku's patents:

22 Endo/Teikoku and Watson agree that the Brand Product provided by  
23 Endo/Teikoku to Watson's Wholesaler Affiliate hereunder is a good-  
24 faith, bargained-for resolution of the claims at issue in the Litigation. The  
25 Brand Product provided hereunder is not contingent on any past or future  
26 purchase of any product from Endo or Teikoku by Watson or any of its  
27 Affiliates. [Agreement, Section 3(i).]

98. Through the Agreement, Defendants ensured that Watson's sales of  
28 Lidoderm would not result in price competition, but rather that Watson would sell  
brand Lidoderm 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 honored by Endo's wholesalers. In fact, Watson maintained the

1    supracompetitive prices for brand Lidoderm throughout the term of the Agreement,  
2    generating revenues and profits of close to \$96 million from those sales. Watson's  
3    sales of branded Lidoderm did not increase output, reduce price, or increase consumer  
4    choice; it merely substituted Watson for Endo as the seller of \$96 million worth of  
5    branded Lidoderm, solely to pay Watson for delaying market entry of its less-  
6    expensive generic Lidoderm.

7           99.    As a second payment in exchange for Watson's promise to delay entry of  
8    its generic Lidoderm product until September 15, 2013, Endo promised to delay  
9    launching an authorized generic version of Lidoderm for 7½ months after Watson's  
10   belated launch of generic Lidoderm, unless another ANDA filer entered the market  
11   during that time (a virtual impossibility that, in fact, did not occur).

12           100.   Endo was otherwise ready, willing, and able to launch an authorized  
13   generic version of Lidoderm simultaneously with Watson's launch. As early as April  
14   2007, Endo and Teikoku had specifically agreed that Endo would be the exclusive  
15   licensee for authorized generic Lidoderm. As shown below, this no-authorized-  
16   generic promise effectuated a payment from Endo and Teikoku to Watson of \$170  
17   million or more.

18           101.   Endo's agreement not to launch an authorized generic meant that Endo  
19   would cede those sales to Watson (and Teikoku would forego any proceeds from such  
20   ceded sales), and Watson would therefore be the sole generic on the market for 7½  
21   months. This would allow Watson to obtain 100% of generic Lidoderm sales for 7½  
22   months (instead of just 50% if Endo had launched an authorized generic) and  
23   additionally permitted Watson to avoid the inter-generic price competition an  
24   authorized generic necessarily creates and thereby maintain an artificially-inflated  
25   supracompetitive generic price for those doubled generic sales. These doubled  
26   revenues and profits were at the expense of Plaintiffs and the members of the Class,  
27

1 consumers, and competition in general. The Agreement (which refers to an authorized  
2 generic by the acronym “AG”) provides:

3 License. Subject to the terms and conditions of this Agreement,  
4 Endo/Teikoku hereby grant to Watson a non-exclusive (other than  
5 pursuant to Section 2(b)), royalty-bearing, non-transferable (other than  
6 pursuant to Section 21) and non-sublicensable (other than pursuant to  
7 Section 2(c)) license to the Licensed Patents to make, have made, import,  
8 use, sell, and offer for sale Watson’s Generic product in the Territory  
9 solely during the License Term. [Settlement Agreement at Section 2(a).]  
10 \*\*\*\*\*

11 AG Product. The license granted pursuant to Section 2(a) shall be  
12 partially exclusive for a period of time in that Endo/Teikoku and their  
13 respective Affiliates shall not market or sell a Generic Product, or  
14 authorize or license a Third Party to market or sell and AG Product at any  
15 time before the earlier of (i) seven and a half (7.5) months from the Start  
16 Date, and (ii) the Launch of any Third Party Generic Product in the  
17 Territory. [Settlement Agreement at Section 2(b) (emphasis added).]

18 102. Endo’s agreement not to launch an authorized generic for 7½ months  
19 allowed Watson to double its generic sales *and* charge higher prices for its generic  
20 during that time (because it faced no competition from an authorized generic), and had  
21 a cash value to Watson of \$170 million or more. This no-authorized-generic promise  
22 is little different than if Endo actually did launch an authorized generic alongside  
23 Watson during the first 7½ months that Watson marketed generic Lidoderm, and then  
24 Endo and Teikoku simply handed their respective portions of the proceeds from those  
25 sales over to Watson in cash. (Though Endo would have to give Watson additional  
26 monies on top of those revenues, to make up for the higher price Watson’s generic  
27 Lidoderm would have been able to command because it was free from price  
28 competition from Endo’s authorized generic).

103. Absent the Reverse Payment Agreement, and Endo’s promise not to  
launch an authorized generic contained therein, Endo would have launched an  
authorized generic simultaneously with Watson’s entry, which would have resulted in  
lower prices to Plaintiffs and the Class, and cut Watson’s revenues and profits from  
selling generic Lidoderm by half.

1           104. In fact, at its first opportunity following the expiration of the no-  
2 authorized-generic promise, Endo immediately launched an authorized generic.

3           105. The Reverse Payment Agreement contained a term whereby Watson  
4 agreed to pay back to Endo a small (25%) portion of Watson's increased profits  
5 resulting from Endo's agreement not to launch an authorized generic for 7½ months.  
6 That term provided: "Beginning with the First Commercial Sale of Watson's Generic  
7 Product and until the date of the occurrence of the First Commercial Sale by a Third  
8 Party or Endo/Teikoku or their Affiliates of a Generic Product or AG Product in the  
9 Territory, Watson shall pay to Endo royalty payments equal to twenty-five percent  
10 (25%) of all Gross Profit of Watson's Generic Product." Agreement, Section 3(a).

11           106. This term providing for a 25% royalty back to Endo during the 7½ month  
12 period was window dressing for the parties' naked agreement not to compete during  
13 Watson's anticipated 180-day Hatch-Waxman exclusivity period. The royalty was  
14 designed merely to give the appearance of a legitimate, non-collusive transaction. In  
15 reality, Defendants simply agreed to lengthen the no-authorized-generic promise's  
16 duration by 1½ months (from 6 months to 7½ months) in order to mitigate the royalty  
17 Watson would be paying to Endo.

18           107. Plaintiffs' estimate that the payment to Watson by the no-authorized-  
19 generic promise amounted to \$170 million or more already accounts for an assumed  
20 25% royalty paid by Watson back to Endo.

21           108. Endo and Teikoku sacrificed substantial revenues and profits by their  
22 agreement not to launch an authorized generic for 7½ months. Absent the Reverse  
23 Payment Agreement and the delay in generic Lidoderm competition it effectuated, it  
24 would have made economic sense for Endo to launch an authorized generic  
25 simultaneous with Watson's launch so that Endo could retain sales that Watson's less  
26 expensive generic otherwise would capture, rather than ceding those sales to Watson.

1 As alleged above, an authorized generic product typically captures approximately 50%  
2 of the generic sales during first 180 days of generic marketing.

3 109. The no-authorized-generic promise was a very large payment to Watson.  
4 Using a conservative approach that relies upon the revenue numbers that Endo  
5 reported in its filings with the Securities and Exchange Commission as an input for the  
6 annual revenue from Lidoderm, and valued as of the time the Reverse Payment  
7 Agreement was entered, Plaintiffs estimate that the no-authorized-generic promise  
8 constituted a payment of \$170 million or more from Endo and Teikoku to Watson.  
9 This figure is estimated by calculating the difference between Watson's revenues  
10 during the 7½ months free from competition from Endo's authorized generic and  
11 Watson's revenues during 7½ months facing competition from Endo's authorized  
12 generic. Both of these amounts can be estimated using the known dynamics of the  
13 pharmaceutical industry and publicly-available information.

14 110. The amount of revenue Watson would expect to earn from sales of  
15 generic Lidoderm during the first 7½ months of marketing free from competition from  
16 Endo's authorized generic can be estimated as follows:

- 17 a. At the time Defendants entered the Agreement, Endo had reported that  
18 its annual revenue from sales of Lidoderm in the prior year, 2011, was  
19 \$825 million. Thus, at the time of the Agreement, 7½ months of  
20 branded Lidoderm sales would generate revenue to Endo of at least  
21 \$515,625,000 ( $7.5/12 * 825,000,000$ ).<sup>1</sup>
- 22 b. As is common in the pharmaceutical industry, the first generic is  
23 expected to take 80% (or more) of the brand's unit sales within six  
24 months. Thus, approximately \$412,500,000 worth of brand unit sales

25 \_\_\_\_\_  
26 <sup>1</sup> That number is conservative, as it does not account for any increase in sales  
27 achieved by Endo in 2012 and 2013, during the period of delayed generic Lidoderm  
competition purchased by Endo and Teikoku's payments to Watson. In fact, Endo's  
Lidoderm revenue rose from \$825 million in 2011 to \$947 million in 2012.

- 1 would be converted to Watson's generic during the first 7½ months  
2 Watson's generic Lidoderm was on the market ( $515,625,000 * .8$ ).
- 3 c. As is also common, with only one generic on the market, the generic  
4 is typically priced at 90% of the brand's pre-generic price, which  
5 would result in generic sales revenues during the first 7½ months  
6 Watson was on the market of approximately \$371,250,000  
7 ( $412,500,000 * .9$ ). Thus, the sales revenues Watson would have  
8 obtained during the 7½ months that the no-authorized-generic promise  
9 was in effect were approximately \$371,250,000.
- 10 d. Under the Agreement, Watson agreed to pay Endo a royalty of 25%  
11 on Watson's gross profits on sales of generic versions of Lidoderm  
12 during the 7½ month period that the no-authorized-generic promise  
13 was in effect. Conservatively applying the royalty on \$371,250,000 in  
14 sales (as opposed to the lower number that would reflect Watson's  
15 gross profits), and further assuming that royalties were actually paid,  
16 this would amount to approximately \$92,812,500 ( $371,250,000 * .25$ ).  
17 As a result, even when the amount of the royalty is netted out,  
18 Watson's anticipated revenue during 7½ months free from  
19 competition from Endo's authorized generic would be, conservatively,  
20 \$278,437,500 ( $371,250,000 - 92,812,500$ ).

21 111. Watson's dramatically smaller revenues if Endo had not promised to  
22 refrain from launching an authorized generic for 7½ months following Watson's  
23 launch can be estimated as follows:

- 24 a. According to an FDA study of the dynamics of generic competition,  
25 the addition of a second generic (such as Endo's authorized generic)  
26  
27



1 drives the average generic price down to 52% of the brand price.<sup>2</sup>

2 Thus, while the generics would still take 80% of brand sales during  
3 those first 7½ months, or \$412,500,000 at the branded Lidoderm price,  
4 the dollar value of those generic sales would drop to \$214,500,000 in  
5 the presence of an authorized generic ( $412,500,000 * .52$ ).

6 b. Watson would not get 100% of those revenues, however. That is  
7 because the unit sales of the generic during those first 7½ months  
8 would be split evenly between Watson's generic Lidoderm and Endo's  
9 authorized generic Lidoderm.<sup>3</sup> (Moreover, there is reason to expect  
10 that Endo may have enjoyed a marketing advantage as the incumbent  
11 and garner more than 50% of unit sales.)

12 c. Thus, without Endo's no-authorized-generic promise, Watson's  
13 revenues from sales of generic Lidoderm during the first 7½ months of  
14 generic marketing would have been approximately \$107,250,000  
15 ( $214,500,000 * .5$ ).

16 112. The incremental revenue that Endo and Teikoku paid to Watson by the  
17 no-authorized-generic promise is therefore \$171,187,500 ( $278,437,500 -$   
18  $107,250,000$ ). That amount is the payment that Endo and Teikoku made to Watson by  
19 way of the no-authorized-generic promise contained in the Reverse Payment  
20 Agreement. This estimate assumes that, rather than Defendants' entering an

21 \_\_\_\_\_  
22 <sup>2</sup> Generic Competition and Drug Prices,  
23 [http://www.fda.gov/AboutFDA/CentersOffices/  
OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm) (last accessed June 3,  
2014).

24 <sup>3</sup> *Id.* at vi (The Federal Trade Commission has concluded that, when free from  
25 competition from an authorized generic, "the first-filer's revenue will approximately  
26 double" during the first six months of generic competition, compared to what the first  
27 filer would make if it faced authorized generic competition.). The Supreme Court has  
recognized this as well. *See FTC v. Actavis*, 133 S. Ct. 2223, 2229 (2013) (the "vast  
majority of potential profits for a generic drug manufacturer materialize during" the  
first six months of marketing).



1 agreement that allowed Watson to enter without Endo and Teikoku paying Watson to  
2 delay its entry, Watson would have entered the market “at risk” in the “but-for world”  
3 (*i.e.*, in a world absent the reverse payments challenged by this lawsuit).

4 113. By contrast, had the parties instead entered an agreement without Endo  
5 and Teikoku paying Watson to delay entry of its generic Lidoderm, and the  
6 Agreement consequently bore an earlier agreed entry date, and assuming a term in that  
7 agreement requiring Watson to pay a royalty of 25% during the first 7½ months of  
8 Watson’s generic marketing, the royalty on those sales would be \$26,812,500  
9 ( $107,250,000 * .25$ ). Thus, net of royalties, the revenue Watson would have realized  
10 during the first 7½ months of marketing from an earlier licensed entry with  
11 competition from Endo’s authorized generic would be \$80,437,500 ( $107,250,000 -$   
12  $26,812,500$ ).

13 114. The incremental revenue that Endo and Teikoku paid to Watson by the  
14 no-authorized-generic promise is therefore approximately \$198,000,000 ( $278,437,500$   
15  $- 80,437,500$ ). That amount is the payment that Endo and Teikoku made to Watson  
16 by way of the no-authorized-generic promise contained in the Reverse Payment  
17 Agreement. This second estimate assumes that, rather than Watson entering the  
18 market at risk, Defendants enter into an agreement that allowed Watson to enter  
19 without Endo and Teikoku paying Watson to delay its entry in the “but-for world”  
20 (*i.e.*, in a world absent the reverse payments challenged by this lawsuit).

21 115. Thus, Endo’s agreement not to launch an authorized generic version of  
22 Lidoderm for 7½ months was a payment to Watson of at least \$170 million and  
23 possibly \$198 million or more. The value of this payment to Watson was no different  
24 than if Endo had made those sales itself (by launching an authorized generic) and then  
25 Endo and Teikoku handed their respective portions of the resulting \$170-198 million  
26 or more to Watson in cash. And, given that Lidoderm revenues increased significantly  
27

1 to \$947 million in 2012, the size of the payment almost certainly increased by the time  
2 Watson ultimately received it in September of 2013, when Watson belatedly launched  
3 without competition from Endo's authorized generic.

4 116. The total payment flowing from Endo and Teikoku to Watson, including  
5 both the \$96 million in free goods and Endo's promise to delay launching an  
6 authorized generic version of Lidoderm for 7½ months had a cash value in the  
7 hundreds of millions of dollars. Although Plaintiffs do not assume the burdens of  
8 production or proof on Defendants' affirmative defenses by so doing, Plaintiffs  
9 nevertheless aver that Defendants can offer no cognizable, nonpretextual justification  
10 or explanation for the reverse payments. The reverse payments are far greater than  
11 Endo and Teikoku's avoided litigation costs, and were not for services to be provided  
12 by Watson to Endo and/or Teikoku. Rather, the reverse payments were made in order  
13 to induce Watson to stay out of the lidocaine patch 5% market until September of  
14 2013 and to allow Defendants to share monopoly profits.

15 117. These large, unjustified payments have no rational connection to, and far  
16 exceed, any approximation of the costs of continuing the patent litigation. Moreover,  
17 Defendants are unable to establish that either payment was consideration for the fair  
18 value of any services provided by Watson to Endo and/or Teikoku. Indeed, Watson  
19 was not required to perform any services in exchange for the unlawful payment  
20 according to the Reverse Payment Agreement. Watson provided no value to Endo or  
21 Teikoku under the Agreement other than impermissible agreement to delay  
22 competition. The Agreement was not a distribution agreement, and Endo had no need  
23 for any such services for Lidoderm in any event.

24 118. Absent Endo and Teikoku's unlawful reverse payments to Watson, any  
25 agreement settling the patent litigation would have resulted in much less delay of  
26 Watson's generic entry than with the payments. But for the reverse payments, Watson  
27

1 would have launched much earlier than September 2013, either under an agreement  
 2 without any reverse payments, or at risk after final approval. And, in either  
 3 circumstance, Watson's entry would have been immediately met with Endo's  
 4 authorized generic.

5 119. The evidence amassed during and prior to the patent litigations showed  
 6 that the patents purportedly covering Lidoderm would not withstand scrutiny.  
 7 Moreover, the millions of dollars that Endo and Teikoku paid to Watson as part of the  
 8 unlawful Agreement "provide a workable surrogate for [the] patent[s'] weakness[es]."  
 9 *FTC v. Actavis, Inc.*, 570 U.S. \_\_\_, 133 S. Ct. 2223, 2236-37 (2013). "An  
 10 unexplained reverse payment," like the payment at issue here, "itself would normally  
 11 suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236.

### 12 **C. Anticompetitive Purpose and Effect of Defendants' Conduct**

13 120. The unlawful Reverse Payment Agreement enabled Defendants to: (a)  
 14 delay the entry of less expensive generic versions of Lidoderm products in the United  
 15 States for up to 13 months; (b) delay the introduction of an authorized generic  
 16 lidocaine patch 5% for 7½ months, which otherwise would have appeared on the  
 17 market coincident with initial generic competition; (c) fix, raise, maintain or stabilize  
 18 the price of lidocaine patch 5% products; (d) maintain a monopoly in the U.S. market  
 19 for lidocaine patch 5% products; (e) allocate 100% of the United States market for  
 20 lidocaine patch 5% to Endo for up to 13 months; and (f) allocate 100% of United  
 21 States sales of generic lidocaine patch 5% to Watson for 7½ months.

22 121. Paragraph deleted.<sup>4</sup>

25 <sup>4</sup> Plaintiffs have deleted this paragraph alleging *per se* illegality of the agreement to  
 26 withhold an authorized generic in light of the Court's ruling (ECF No. 117, at 26-27,  
 27 November 17, 2014). Plaintiffs preserve their appellate rights with respect to the  
 ruling dismissing Plaintiffs' count alleging that the agreement to withhold an  
 authorized generic is *per se* unlawful.

1           122. But for the unlawful Agreement: (a) Watson would have begun selling its  
2 generic version of Lidoderm when it received FDA approval on August 23, 2012 or  
3 shortly thereafter, either “at risk” or pursuant to an agreement with Endo and Teikoku  
4 that did not include a reverse payment; and (b) Endo would have launched an  
5 authorized generic lidocaine patch 5% simultaneously with Watson’s earlier entry.

6           123. Watson would have launched its generic product notwithstanding any  
7 patents that Endo and Teikoku may have claimed covered Lidoderm, prior to  
8 resolution of the ’529 Litigation, and prior to resolution of the Rolf Patent Litigation.  
9 None of the patents other than the ’529 patent was even listed in the Orange Book  
10 when Watson filed its ANDA. Thus, Watson was not required to certify to any other  
11 patents under Hatch-Waxman, and any litigation filed over those other patents would  
12 not, and could not, result in a 30 month Hatch-Waxman stay of FDA approval of  
13 Watson’s ANDA. Given the obvious defects in the ’529 patent and Rolf patents,  
14 Watson would have launched upon final FDA approval even in the absence of a court  
15 ruling on those patents. Once Watson obtained FDA approval of its ANDA, it was  
16 free to launch, and but for the unlawful reverse payments, Watson would have  
17 launched its generic Lidoderm immediately, and Endo would have launched an  
18 authorized generic simultaneously.

19           124. Watson told Wall Street analysts in late 2011 and early 2012 that it was  
20 pursuing its ANDA, that it was closely monitoring the progress of the ANDA and  
21 expected approval in 2012, that its efforts to increase capacity were well underway,  
22 and it expected to be “ready to go at the earliest possible time to launch the product.”

23           125. Alternatively, but for the unlawful reverse payments Endo, Teikoku and  
24 Watson would have entered into a procompetitive settlement agreement under which  
25 Endo and Teikoku would not have paid Watson for delay, Watson would have entered  
26  
27

1 the market much earlier than September of 2013, and Endo would have  
2 simultaneously launched an authorized generic lidocaine patch 5%.

3 126. Defendants' unlawful actions have delayed the sale of generic Lidoderm  
4 in the United States, delayed the sale of an authorized generic Lidoderm in the United  
5 States, and unlawfully enabled Endo, and then Watson, to sell lidocaine patch 5% at  
6 artificially inflated, supracompetitive prices. But for Defendants' illegal conduct,  
7 generic competition to Lidoderm would have begun prior to September 15, 2013, and  
8 would have included both Watson's generic Lidoderm product as well as Endo's  
9 authorized generic Lidoderm.

#### 10 **VIII. INTERSTATE COMMERCE**

11 127. At all material times, Teikoku manufactured and Endo promoted,  
12 distributed, and sold substantial amounts of Lidoderm (and Watson manufactured,  
13 promoted, distributed, and sold substantial amounts of generic Lidoderm) in a  
14 continuous and uninterrupted flow of commerce across state and national lines and  
15 throughout the United States, including its territories, possessions and the  
16 Commonwealth of Puerto Rico.

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

21 129. In furtherance of their efforts to monopolize and restrain competition in  
22 the market for lidocaine patch 5%, Defendants employed the United States mail and  
23 interstate and international telephone lines, as well as means of interstate and  
24 international travel. The activities of Defendants were within the flow of and have  
25 substantially affected interstate commerce.  
26  
27

**IX. MONOPOLY POWER AND MARKET DEFINITION**

1  
2 130. At all relevant times, Endo had market and/or monopoly power over  
3 lidocaine patch 5% because it had the power to maintain lidocaine patch 5% prices at  
4 supracompetitive levels without losing substantial sales to other products prescribed  
5 and/or used for the same purposes as Lidoderm, with the exception of AB-rated  
6 generic versions of Lidoderm.

7 131. A small but significant, non-transitory price increase to Lidoderm by  
8 Endo would not have caused a significant loss of sales to drug products other than AB-  
9 rated generic versions of Lidoderm.

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

13 133. Because of, among other reasons, its approved indication, Lidoderm is  
14 differentiated from all products other than AB-rated generic versions of Lidoderm.

15 134. Endo needed to control only Lidoderm and its AB-rated generic  
16 equivalents, and no other products, in order to maintain the price of Lidoderm  
17 profitably at supracompetitive prices. Only the market entry of a competing, AB-rated  
18 generic version of Lidoderm would render Endo unable to profitably maintain its  
19 supracompetitive prices for Lidoderm without losing substantial sales.

20 135. Endo sold Lidoderm at prices well in excess of marginal costs, and in  
21 excess of the competitive price, and enjoyed high profit margins.

22 136. Endo has had, and exercised, the power to exclude and restrict  
23 competition to Lidoderm and its AB-rated generics.

24 137. Endo and Teikoku's reverse payments to Watson demonstrate that Endo  
25 enjoyed market and/or monopoly power with respect to lidocaine patch 5%.  
26  
27

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

4 139. To the extent that Plaintiffs may be legally required to prove market  
5 and/or monopoly power circumstantially by first defining a relevant product market,  
6 Plaintiffs allege that the relevant market is lidocaine patch 5% (*i.e.*, Lidoderm and its  
7 AB-rated generic equivalents). During the period relevant to this case, Endo was able  
8 to profitably maintain the price of lidocaine patch 5% well above competitive levels.

9 140. The relevant geographic market is the United States, including its  
10 territories, possessions and the Commonwealth of Puerto Rico.

11 141. At all relevant times, Endo's market share in the relevant market was  
12 100%, implying a substantial amount of market power.

13 **X. EFFECTS ON COMPETITION AND DAMAGES**

14 142. Watson's ANDA was approved August 23, 2012. Were it not for the  
15 unlawful reverse payments and Reverse Payment Agreement alleged herein, Watson  
16 would have entered the market on or shortly after that date. One or more generic  
17 Lidoderm products would have entered the market well before the date provided in  
18 Defendants' unlawful Reverse Payment Agreement, September 15, 2013.

19 143. But for the unlawful Reverse Payment Agreement, an authorized generic  
20 version of Lidoderm would have been available on the market simultaneously with the  
21 launch of Watson's generic.

22 144. Defendants' unlawful reverse payments and Reverse Payment Agreement  
23 delayed generic Lidoderm competition and unlawfully enabled Endo to sell Lidoderm  
24 without generic competition. But for Defendants' illegal conduct, one or more generic  
25 competitors would have begun marketing AB-rated generic versions of Lidoderm on  
26  
27



1 August 23, 2012 or shortly thereafter, and in any event, earlier than September 15,  
2 2013.

3 145. Watson had extensive experience in the pharmaceutical industry,  
4 including in obtaining approval for ANDAs, marketing generic pharmaceutical  
5 products, and manufacturing commercial launch quantities adequate to meet market  
6 demand.

7 146. Defendants' unlawful Reverse Payment Agreement, which delayed  
8 introduction of generic versions of Lidoderm in the United States, has caused  
9 Plaintiffs and the Class to pay more than they would have paid for lidocaine patch 5%.

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

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

22 149. But for Defendants' unlawful Agreement, direct purchasers, such as  
23 Plaintiffs and members of the Class, would have paid less for lidocaine patch 5% by  
24 (a) substituting purchases of less-expensive AB-rated generic Lidoderm for their  
25 purchases of more-expensive brand Lidoderm, (b) receiving discounts on their  
26  
27

1 remaining brand Lidoderm purchases, and/or (c) purchasing generic Lidoderm at  
2 lower prices sooner.

3 150. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of  
4 the benefits of competition that the antitrust laws were designed to protect.

5 151. During the relevant period, Plaintiffs and other members of the Class  
6 purchased substantial amounts of Lidoderm directly from Endo and purchased  
7 substantial amounts of generic Lidoderm directly from Watson. As a result of  
8 Defendants' illegal conduct as alleged herein, Plaintiffs and other members of the  
9 Class were compelled to pay, and did pay, artificially inflated prices for their lidocaine  
10 patch 5% requirements. Plaintiffs and the other Class members paid prices for  
11 lidocaine patch 5% that were substantially greater than the prices that they would have  
12 paid absent the illegal conduct alleged herein, because: (1) Class members were  
13 deprived of the opportunity to purchase lower-priced generic Lidoderm instead of  
14 more expensive brand Lidoderm; and (2) Class members paid artificially inflated  
15 prices for lidocaine patch 5%.

16 152. As a consequence, Plaintiffs and other members of the Class have  
17 sustained substantial losses and damage to their business and property in the form of  
18 overcharges, the exact amount of which will be the subject of proof at trial.

## 19 **XI. CLAIMS FOR RELIEF**

### 20 **CLAIM I: VIOLATION OF 15 U.S.C. § 1** 21 **(AGREEMENT UNREASONABLY RESTRAINING TRADE)**

22 153. Plaintiffs hereby incorporate each preceding and succeeding paragraph as  
23 though fully set forth herein.

24 154. Defendants have engaged in an unlawful contract, combination, or  
25 conspiracy that has unreasonably restrained trade or commerce in violation of Section  
26 1 of the Sherman Act, 15 U.S.C. § 1.

1            155. In or about May 2012 and at times prior to the formal execution thereof  
2 Defendants entered into the Reverse Payment Agreement, an illegal contract,  
3 combination and conspiracy in restraint of trade under which Endo and Teikoku  
4 agreed to make large reverse payments to Watson in exchange for Watson's  
5 agreement to delay bringing its generic version of Lidoderm to the market for up to 13  
6 months, the purpose and effect of which were to: (a) allocate 100% of the market for  
7 lidocaine patch 5% in the United States, including its territories, possessions and the  
8 Commonwealth of Puerto Rico, to Endo; (b) delay the availability of generic versions  
9 of Lidoderm in the United States, including its territories, possessions and the  
10 Commonwealth of Puerto Rico, thereby protecting Lidoderm from any generic  
11 competition; (c) delay the entry of Endo's authorized generic until 7½ months after  
12 Watson's entry with a generic Lidoderm product, and allocate 100% of sales for  
13 generic lidocaine patch 5% in the United States, including its territories, possessions  
14 and the Commonwealth of Puerto Rico, to Watson prior to that time; and (d) fix, at  
15 supracompetitive levels, the price at which direct purchasers would pay for lidocaine  
16 patch 5%.

17            156. The Agreement harmed Plaintiffs and the Class as set forth above.

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

19            158. There is and was no legitimate, non-pretextual, procompetitive  
20 justification for the payment from Endo and Teikoku to Watson that outweighs its  
21 harmful effect. Even if there were some conceivable such justification, the payment  
22 was not necessary to achieve, nor the least restrictive means of achieving, such a  
23 purpose.

24            159. As a direct and proximate result of Defendants' agreement in restraint of  
25 trade, as alleged herein, Plaintiffs and the Class were harmed and suffered overcharge  
26 damages as aforesaid.

**CLAIM II: Deleted<sup>5</sup>**

160. Paragraph deleted.

161. Paragraph deleted.

162. Paragraph deleted.

163. Paragraph deleted.

164. Paragraph deleted.

165. Paragraph deleted.

166. Paragraph deleted.

167. Paragraph deleted.

**CLAIM III: VIOLATION OF 15 U.S.C. § 2  
(CONSPIRACY TO MONOPOLIZE)**

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

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

170. Through the Reverse Payment Agreement, Endo, Teikoku and Watson conspired to maintain Endo's monopoly power in the relevant market in order to block and delay market entry of generic Lidoderm.

171. The Reverse Payment Agreement (a) allocated 100% of the market for lidocaine patch 5% in the United States, including its territories, possessions and the Commonwealth of Puerto Rico, to Endo; (b) delayed the availability of generic versions of Lidoderm in the United States, including its territories, possessions and

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<sup>5</sup> Plaintiffs have deleted Count II alleging *per se* illegality of the agreement to withhold an authorized generic in light of the Court's ruling (ECF No. 117, at 26-27, November 17, 2014). Plaintiffs preserve their appellate rights with respect to the ruling dismissing Plaintiffs' count alleging that the agreement to withhold an authorized generic is *per se* unlawful.

1 the Commonwealth of Puerto Rico, thereby protecting Lidoderm from any generic  
2 competition; (c) delayed the entry of Endo's authorized generic until 7½ months after  
3 Watson's entry with a generic Lidoderm product, and allocate 100% of sales for  
4 generic lidocaine patch 5% in the United States, including its territories, possessions  
5 and the Commonwealth of Puerto Rico, to Watson prior to that time; and (d) fixed, at  
6 supracompetitive levels, the price at which direct purchasers would pay for lidocaine  
7 patch 5%.

8 172. The goal, purpose and/or effect of the Agreement was to maintain and  
9 extend Endo's monopoly power in the United States market, including its territories,  
10 possessions and the Commonwealth of Puerto Rico, in the market for lidocaine patch  
11 5%, in violation of Sherman Act Section 2, 15 U.S.C. § 2. The Agreement was  
12 intended to and did prevent and/or delay generic competition to Lidoderm and enabled  
13 Endo to continue charging supracompetitive prices for Lidoderm without a substantial  
14 loss of sales.

15 173. Defendants knowingly and intentionally conspired to maintain and  
16 enhance Endo's monopoly power in the relevant market.

17 174. Defendants specifically intended that their Agreement would maintain  
18 Endo's monopoly power in the relevant market, and injured Plaintiffs and the Class  
19 thereby.

20 175. Defendants each committed at least one overt act in furtherance of the  
21 conspiracy.

22 176. As a direct and proximate result of Defendants' concerted monopolistic  
23 conduct, as alleged herein, Plaintiffs and the Class were harmed as aforesaid.

24 **COUNT IV: VIOLATION OF 15 U.S.C. § 2**  
25 **(MONOPOLIZATION)**

1 177. Plaintiffs hereby incorporate each preceding and succeeding paragraph as  
2 though fully set forth herein.

3 178. This claim is pled as to Endo only.

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

7 180. Through the anticompetitive conduct, as alleged extensively above, Endo  
8 willfully maintained its monopoly power in the relevant market using restrictive or  
9 exclusionary conduct, rather than by means of greater business acumen, and injured  
10 Plaintiffs and the Class thereby.

11 181. It was Endo's conscious object to further its dominance in the relevant  
12 market by and through the anticompetitive conduct alleged herein.

13 182. Endo's anticompetitive conduct harmed competition as alleged herein.

14 183. As a direct and proximate result of Endo's illegal and monopolistic  
15 conduct, as alleged herein, Plaintiffs and the Class were harmed as alleged herein.

16 **COUNT V: VIOLATION OF 15 U.S.C. § 2**  
17 **(ATTEMPTED MONOPOLIZATION)**

18 184. Plaintiffs hereby incorporate each preceding and succeeding paragraph as  
19 though fully set forth herein.

20 185. This claim is pled as to Endo only.

21 186. Through the Reverse Payment Agreement, Endo specifically intended to  
22 maintain monopoly power in the relevant market. It was Endo's conscious objective  
23 to control prices and/or to exclude competition in the relevant market.

24 187. The natural and probable consequence of Endo's anticompetitive  
25 conduct, which was intended by Endo, and plainly foreseeable to Endo, was to control  
26 prices and exclude competition in the relevant market, to the extent it did not succeed.  
27

1 188. There was a substantial and real chance, a reasonable likelihood, and/or a  
2 dangerous probability that Endo would succeed in and achieve its goal of maintaining  
3 monopoly power in the relevant market.

4 189. As a direct and proximate result of Endos illegal and monopolistic  
5 conduct, Plaintiffs and the Class were harmed as alleged herein.

6 **XII. DEMAND FOR JUDGMENT**

7 WHEREFORE, Plaintiffs, on behalf of themselves and the Class, respectfully  
8 request that the Court:

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

13 B. Enter joint and several judgments against Defendants and in favor of  
14 Plaintiffs and the Class;

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

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

19 **XIII. JURY DEMAND**

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



1 Dated: December 19, 2014

Respectfully submitted,

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