[Submitting Counsel on Signature Page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re LIDODERM ANTITRUST LITIGATION	MDL Docket No. 14-md-02521-WHO
THIS DOCUMENT RELATES TO: ALL END-PAYOR CASES	**END-PAYOR PLAINTIFFS' CORRECTED THIRD CONSOLIDATED AMENDED COMPLAINT** **CLASS ACTION** **DEMAND FOR JURY TRIAL**

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Plaintiffs Allied Services Division Welfare Fund, City of Providence, International Union of Operating Engineers Local 49 Health and Welfare Fund, International Union of Operating Engineers Local 132 Health and Welfare Fund, Iron Workers District Council of New England Welfare Fund, NECA-IBEW Welfare Trust Fund, United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C, 137R, Letizia Gallotto, Irene Kampanis, and Steven Roller, on behalf of themselves and all others similarly situated, file this Corrected Third Consolidated Amended Class Action Complaint against Defendants Endo Pharmaceuticals Inc. ("Endo"), Teikoku Pharma USA ("Teikoku Pharma"), Teikoku Seiyaku Co., Ltd. ("Teikoku Seiyaku" and together with Teikoku Pharma "Teikoku"), Watson Pharmaceuticals, Inc., Actavis plc f/k/a Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc. (collectively "Watson") (together with Endo and Teikoku, the "Defendants") and allege as follows based on: (a) personal knowledge; (b) the investigation of its counsel; and (c) information and belief.

I. NATURE OF THE ACTION

1. This is a civil antitrust action brought by Plaintiffs on behalf of a proposed class of end-payors who indirectly purchased, reimbursed or otherwise paid for lidocaine patch 5%. Lidocaine patch 5%, sold by Endo under the brand name Lidoderm, is used for the treatment of pain associated with post-herpetic neuralgia (a complication associated with shingles). Plaintiffs seek overcharge damages and other relief arising out of Endo and Teikoku's unlawful agreement with Watson not to compete in the market for lidocaine patch 5% in exchange for hundreds of millions of dollars worth of economic incentives provided by Endo and Teikoku. Lidoderm had annual U.S. sales of approximately $1.2 billion by the start of 2012.

2. On May 28, 2012, in the context of settling two patent infringement lawsuits relating to several of Endo and Teikoku's Lidoderm patents, the Defendants entered into an unlawful non-competition agreement that provided for two large and unjustified payments to Watson in exchange for Watson's agreement to delay marketing its less expensive generic version of Lidoderm for more than a year. The first was a payment of at least $96 million worth of branded Lidoderm provided at no cost to Watson. Because Watson was free to sell the branded Lidoderm product and retain the full proceeds of

those sales, this payment was no different than if Endo and Teikoku had paid Watson $96 million in cash. The second payment was a promise by Endo and Teikoku not to launch an "authorized generic" version of Lidoderm for 7½ months after Watson launched its generic. Watson was granted final approval from the Food and Drug Administration (FDA) to launch its generic lidocaine patch 5% on August 23, 2012. But given its obligations under the Defendants' May 28, 2012 agreement (the "Agreement" or the "Reverse Payment Agreement"), Watson did not launch its generic Lidoderm product until more than a year later, in September 2013.

3. But for Defendants' unlawful Agreement, at least one generic version of Lidoderm would have been marketed and sold in the United States as early as August 2012. And but for Defendants' unlawful Agreement, Plaintiffs and the members of the Class would have been able to fulfill their lidocaine patch 5% needs at significantly lower prices far earlier than they did, instead of being forced to pay for branded and generic Lidoderm at higher prices.

4. Defendants' unlawful Agreement was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patch 5% in the United States; (b) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products, even after generic entry; (d) allocate 100% of the United States lidocaine patch 5% market to Endo for up to 13 months; and (e) allocate 100% of the United States lidocaine patch 5% market to Watson for up to 7½ months.

5. As alleged in more detail below, Defendants violated various state antitrust and consumer protection laws enumerated below through their anticompetitive Agreement with Watson to improperly delay competition from lower-priced generic versions of Lidoderm.

II. JURISDICTION, VENUE, AND INTRADISTRICT ASSIGNMENT

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. section 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, there are more than one hundred members of the Class, and at least one member of the proposed Class is a citizen of a state different from that of one of the Defendants.

7. Jurisdiction and venue are proper in this Court under 28 U.S.C. section 1391 because Defendants transact business in this District and Defendant Teikoku Pharma's principal place of business is in this District. A substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this District. The acts complained of have and will continue to have substantial effects in this District.

8. Assignment to this division in this District is proper because the interstate trade and commerce involved and affected was and is carried out within this division, and this action has been transferred to this division by the Judicial Panel on Multidistrict Litigation.

III. PARTIES

A. Plaintiffs

9. Plaintiff Allied Services Division Welfare Fund ("ASD") is an employee health and welfare benefit plan with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005. Plaintiff ASD indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Kansas at supracompetitive prices during the Class Period, and was thereby injured.

10. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island 02903. Plaintiff Providence indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in California, Connecticut, Florida, Georgia, Maine, Massachusetts, Rhode Island and Texas, at supracompetitive prices during the Class Period, and was thereby injured.

11. Plaintiff International Union of Operating Engineers Local 49 Health and Welfare Fund ("Local 49") is an employee health and welfare benefit plan with its principal place of business at 2829 Anthony Lane S., Minneapolis, Minnesota 55418. Plaintiff Local 49 indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Arkansas, Minnesota, North Dakota, South Dakota and Wisconsin, at supracompetitive prices during the Class Period, and was thereby injured.

12. Plaintiff International Union of Operating Engineers Local 132 Health and Welfare Fund ("Local 132") is an employee health and welfare benefit plan with its principal place of business at 636 Fourth Avenue, Huntington, West Virginia 25701. Plaintiff Local 132 indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Florida, Illinois, North Carolina, Pennsylvania and West Virginia, at supracompetitive prices during the Class Periods, and was thereby injured.

13. Plaintiff Iron Workers District Council of New England Welfare Fund ("Iron Workers") is an employee health and welfare benefit plan with its principal place of business at 161 Granite Avenue, Dorchester, Massachusetts 02124. Plaintiff Iron Workers indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Maine, Massachusetts, Missouri, New Hampshire, New Jersey and Rhode Island, at supracompetitive prices during the Class Period, and was thereby injured.

14. Plaintiff NECA-IBEW Welfare Trust Fund ("NECA") is an employee health and welfare benefit plan with its principal place of business at 2120 Hubbard Avenue, Decatur, Illinois 62526. Plaintiff NECA indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Alabama, Arizona, Colorado, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Minnesota, Missouri, Nevada, New Mexico, New York, North Carolina, Ohio, South Dakota, Tennessee, Texas, Utah and Wisconsin, at supracompetitive prices during the Class Period, and was thereby injured.

15. Plaintiff United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund ("UFCW") is an employee health and welfare benefit plan with its principal place of business at 3031-A Walton Road, Plymouth Meeting, Pennsylvania 19462. Plaintiff UFCW indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Delaware, New Jersey, North Carolina, Pennsylvania and South Carolina, at supracompetitive prices during the Class Period, and was thereby injured.

16. Plaintiff Welfare Plan of the International Union of Operating Engineers Locals 137, 137A, 137B, 137C, 137R ("Local 137") is an employee health and welfare benefit plan with its principal

place of business at 1360 Pleasantville Road, Briarcliff Manor, New York 10510. Plaintiff Local 137 indirectly purchased, paid and/or provided reimbursement for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Florida, New York, and Pennsylvania, at supracompetitive prices during the Class Period, and was thereby injured.

17. Plaintiff Letizia Gallotto is an individual who resides in Suffolk County in the Commonwealth of Massachusetts. Ms. Gallotto indirectly purchased and paid for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in Massachusetts, at supracompetitive prices during the Class Period, and was thereby injured.

18. Plaintiff Irene Kampanis is an individual who resides in Nassau County in the State of New York. Ms. Kampanis indirectly purchased and paid for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in New York, at supracompetitive prices during the Class Period, and was thereby injured.

19. Plaintiff Steven Roller is an individual who resides in San Diego County in the State of California. Mr. Roller indirectly purchased and paid for Lidoderm and/or the generic version of Lidoderm once it became available, other than for resale, in California, at supracompetitive prices during the Class Period, and was thereby injured.

B. Defendants

20. Defendant Endo Pharmaceuticals Inc. is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania, 19355. Endo markets and sells Lidoderm throughout the United States.

21. Defendant Teikoku Seiyaku is a company organized and existing under the laws of Japan, having its principal place of business in Higashikagawa, Kagawa, Japan. Teikoku Seiyaku is the assignee of U.S. Patent No. 5,827,529, which was the subject of a patent lawsuit filed by Endo and Teikoku against Watson. Teikoku Seiyaku manufactures Lidoderm in Japan for commercial sale in the United States by Endo under a Supply and Manufacturing Agreement with Endo. Endo pays Teikoku Seiyaku royalties under that agreement, as amended. Teikoku Seiyaku does not sell Lidoderm to purchasers in the United States.

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

23. Defendant Actavis plc is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland and a place of business in Morris Corporate Center III, 400 Interpace Parkway Parsippany, New Jersey 07054. Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc. in January 2013 as a result of Watson Pharmaceuticals, Inc.'s acquisition of Swiss-based Actavis Group on or around October 2012. On or about October 1, 2013, Actavis, Inc. changed its name to Actavis plc.

24. Defendant Watson Pharmaceuticals, Inc. was a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California. Effective on or about January 24, 2013, Watson Pharmaceuticals, Inc. changed its name to Actavis, Inc., which later became Actavis plc.

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

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

27. All of Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered and/or performed by Defendants' various officers, agents, employees or other representatives while actively engaged in the management

of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, with the actual, apparent and/or ostensible authority of Defendants.

28. With respect to all of the conduct complained of below, at all relevant times Endo acted in concert with Teikoku Pharma and Teikoku Seiyaku. Moreover, Endo, Teikoku Pharma and Teikoku Seiyaku each signed the Agreement with Watson. Furthermore, Endo, Teikoku Pharma and Teikoku Seiyaku at all relevant times acted in concert with respect to the material provisions and performance of the Agreement, which refers to Endo, Teikoku Pharma and Teikoku Seiyaku collectively in provisions relating to the grant of patent licenses to Watson, the promise not to launch a competing authorized generic for 7½ months, and the obligation to deliver free brand Lidoderm product to pay Watson. On information and belief, Endo, Teikoku Pharma and Teikoku Seiyaku are involved in a marketing enterprise that covers the distribution and marketing of Lidoderm in the United States.

IV. CLASS ACTION ALLEGATIONS

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

> All persons or entities
>
> (1) in the United States, the District of Columbia, and Puerto Rico who indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for branded or generic Lidoderm in Arizona, California, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia, and/or
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> (2) who reside in Arizona, California, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia and indirectly purchased, paid and/or provided reimbursement for some or all of the purchase price for branded or generic Lidoderm in the United States, the District of Columbia, or Puerto Rico
>
> for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries (the "Class" or the "End-Payor Class"), other than for resale at any time during the period August 23, 2012, through the date the anticompetitive effects of Defendants' challenged conduct cease (the "Class Period").

30. The following persons or entities are excluded from the proposed End-Payor Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All federal or state governmental entities, excluding cities, towns, or municipalities with self-funded prescription drug plans;

c. All persons or entities who purchased Lidoderm or its AB-rated generic equivalent for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans, *i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members;

e. Any "flat co-pay" consumers whose purchases were paid in part by a third- party payor and whose co-payment was the same regardless of the retail purchase price;

f. Pharmacy Benefits Managers; and

g. The judges in this case and any members of their immediate families.

31. Members of the Class are so numerous that joinder is impracticable. Members of the Class are widely dispersed throughout the country. Plaintiffs believe the Class includes hundreds of thousands, if not millions, of consumers and thousands of third-party payors.

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

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

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

35. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual Class members, because Defendants have acted on grounds generally applicable to the entire Class.

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

a. whether the pay-for-delay conduct alleged herein constitutes a violation of the state laws listed below;

b. whether Defendants conspired to and did suppress generic competition to Lidoderm;

c. whether, pursuant to the Agreement, Watson agreed to and did delay its entry into the market with generic Lidoderm;

d. whether, pursuant to the Agreement, Endo and Teikoku made large, unjustified payments Watson;

e. whether there are legitimate procompetitive justifications explaining Endo and Teikoku's payments to Watson;

f. whether Defendants' challenged conduct harmed competition in the lidocaine patch 5% market;

g. whether Defendants conspired to maintain Endo's market power in the lidocaine patch 5% market;

h. whether Endo possessed market power over lidocaine patch 5%;

i. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;

j. whether Defendants' conduct as alleged herein has substantially affected interstate and/or intrastate commerce;

k. whether, and to what extent, Defendants' conduct as alleged herein caused antitrust injury to the business or property of Plaintiffs and the members of the Class in the nature of overcharges; and

l. the quantum of aggregate overcharge damages paid by the Class.

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

individually, substantially outweigh any difficulties that may arise in the management of this class action.

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

V. REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

39. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a manufacturer who creates a new drug must obtain the approval of FDA to sell the new drug by filing a New Drug Application (NDA). 21 U.S.C. §§ 301-392. A NDA must include submission of specific data concerning the safety and effectiveness of the drug, and identify any patent that allegedly claims either the approved drug or approved methods of use of the drug and could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand drug prior to the expiration of the listed patent(s). 21 U.S.C. section 355(a), (b). When the FDA approves an NDA, it publishes the patents identified by the brand manufacturer in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within thirty days of issuance. 21 U.S.C. §§ 355(b)(1) & (c)(2).

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

1. The Hatch-Waxman Amendments

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

as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. *See generally* 21 U.S.C. 21 U.S.C. § 355(j) *et seq*.

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

43. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" rating by the FDA, allowing their substitution for the brand when an end-payor presents a prescription for the brand product.

44. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues, and a growing threat to brand name drug profits. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014).

2. Paragraph IV Certifications

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

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

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

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

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

46. When a generic manufacturer files a Paragraph IV certification it must promptly provide notice to the brand manufacturer. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement regardless of the merits of the action. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval, but for the 30-month stay. As a practical matter, the initiation of a patent infringement action provides the brand manufacturer with the equivalent of an automatic 30-month injunction that prevents the generic manufacturer from releasing a competing generic product, regardless of the merits of the infringement action.

3. Citizen Petitions to the FDA

47. Federal regulations governing the FDA create a mechanism by which a person or entity may file a petition requesting, among other things, that the agency take or refrain from taking any form of administrative action. This is commonly referred to as a "citizen petition." 21 C.F.R. § 10.30.

48. The citizen petition process is intended to provide an opportunity for persons to express genuine concerns about the safety or efficacy of a product.

49. Reviewing and responding to citizen petitions is often a resource-intensive and time consuming task, regardless of the merits of the petition, because the FDA must research the petition's

subject matter, examine scientific, medical, legal and sometimes economic issues, consider public response to the petition and coordinate internal agency review and clearance of the petition response.

50. On March 12, 2012, Endo filed a citizen petition – which was an amendment to two prior petitions – requesting that the FDA take fourteen specific actions with regard to lidocaine 5% generics. At the time Endo submitted its citizen petition and amendments concerning Lidoderm, the FDA had a well-known practice of withholding both tentative and final ANDA approval until after its consideration of and response to a citizen petition was complete.

51. The citizen petition process has been subject to misuse and abuse by many brand manufacturers as a tactic to extend their monopolies on certain brand drugs. Often citizen petitions that seek to delay approval of generic ANDAs fail to raise legitimate concerns about the safety or efficacy of generic products, but instead seek to preserve monopolies after the end of a statutorily-granted patent or FDA exclusivity period. Final approval of a pending ANDA is often delayed for several months, or even years, while the FDA evaluates the citizen petition.

B. Generic Versions of Brand Drugs Take Significant Sales From the Corresponding Brand Versions

52. Generic versions of branded drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective, as their branded counterparts. Generic drugs that are therapeutically equivalent to their brand counterparts are given an "AB" equivalent rating by the FDA. The only material difference between generic drugs and branded drugs is their price: when there is a single generic drug competitor during the first 180 days of generic marketing, the generic drugs cost on average 82% as much as their branded drug counterparts did before generic entry. The discount typically becomes deeper as time goes on as multiple generic drug manufacturer competitors enter the market for a given branded drug. One year after generic entry, generic drugs cost, on average, 15% as much as the branded drug cost prior to generic entry. The Federal Trade Commission (FTC) estimates that about one year after market entry, a generic drug takes over 90% of the branded drug's unit sales.

FTC Staff, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010).[1] The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. In fact, "[a]ccording to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[2]

53. In every state, pharmacists are permitted (and, in some states, required) to substitute a generically-equivalent product for the brand product prescribed, unless the doctor has indicated that the prescription for the brand product must be "dispensed as written." Because of the price differentials, and other institutional features of the pharmaceutical industry, generic versions are liberally and substantially substituted by pharmacists when an end-payor presents a prescription for the brand counterpart.

54. There is an incentive to choose the less expensive generic drug equivalent in every link in the prescription drug chain. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generic drugs than on branded drugs. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic drugs for more expensive branded drugs. Health insurers are contractually obligated to pay for the bulk of their insureds' prescriptions, whether filled with branded drugs or generic drugs, so they offer lower co-pays for generic drugs to encourage their use.

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

56. Until a generic manufacturer enters the market, however, there is no bioequivalent generic drug to substitute for and otherwise compete with the brand drug, and the brand manufacturer can therefore continue to charge supracompetitive prices profitably without losing a substantial portion of its brand sales. Consequently, brand manufacturers have a strong incentive to use various tactics,

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[1] *Available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed June 7, 2015).

[2] *See* FDA, What Are Generic Drugs?, http://www.fda.gov/Drugs/ResourcesForYou/Consumers%20/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm (last accessed June 7, 2015).

including reverse payment, market allocation agreements not to compete, to delay the introduction of generic competition into the market. For Endo and Teikoku, that incentive was particularly strong: in 2012 Lidoderm accounted for 31% of Endo's revenues and Endo purchased $179.5 million in Lidoderm from Teikoku and paid Teikoku $55.7 million in royalties.

C. No-Authorized Generic Promises Are a Means by Which Brand Manufacturers Pay Generic Manufacturers to Delay Generic Competition

57. Generic companies generally make about 80% of their total income on a generic product when that product is the sole generic equivalent of the corresponding branded drug. To regain some of the revenue lost as a result of the termination of brand exclusivity that would otherwise go to the competing generic, brand manufacturers will often launch their own "authorized generic" version of the branded drug. An authorized generic is the branded drug that is sold as a generic product under the brand product's original NDA. Because the brand manufacturer already has approval to sell its branded drug, it does not need to file an ANDA, or obtain any additional approvals, to market an identical generic version of its own brand drug. ANDA filers have no patents on, and no ability to prevent the brand manufacturer from launching, an authorized generic version of the brand drug.

58. For the brand company, an authorized generic provides a low cost, low risk means to regain some of the revenue lost from the termination of brand exclusivity. For a generic manufacturer, however, an authorized generic launch has a substantial negative impact on its revenue. If a brand manufacturer launches an authorized generic when there is only one generic one product on the market, it typically prices its authorized generic competitively as against the non-authorized generic and thus captures approximately 50% of total generic sales during that period.

59. To prevent this 50% loss of revenue from an authorized generic launch, a generic manufacturer that would otherwise have the only generic product on the market may be willing to delay its market entry in return for the brand company's agreement to refrain from launching a competing authorized generic for a period of time after the generic manufacturer begins to market its product, as Endo and Teikoku agreed to do so here. A brand manufacturer's promise not to launch an authorized generic during the initial period of generic marketing is a very valuable payment to a generic company that has the only generic product on the market during that time. The promise doubles the generic

entrant's sales volume during that time, and because it removes a source of price competition from the market, it more than doubles the generic entrant's revenues and profits. Correspondingly, a brand's promise not to launch an authorized generic represents a substantial sacrifice of the revenues and profits that the authorized generic would otherwise have created for the brand. Those revenues and profits are instead ceded, by way of the no-authorized generic promise, to the generic company.

60. In a report by the FTC issued at the request of Congress in 2011 entitled *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*[3], the FTC concluded that no-authorized generic agreements have become a common form of payment from brands to generics to induce delayed generic entry. The FTC analyzed documents and empirical data covering more than 100 companies and found that the presence of authorized generic competition can reduce a generic's revenues by 40-52% during the first 180 days of generic marketing when there are no other generics on the market. *Id*. at iii. The FTC found that a generic company makes significantly less money when it competes with an authorized generic because (1) the authorized generic takes a significant share of generic sales away from the first-filer (around 40-50%), and (2) wholesale and retail prices decrease when the first generic product faces competition from an authorized generic due to competition between the two. Both of these factors reduce the generic company's sales and revenues. With a no-authorized generic promise, the generic company avoids this reduction in revenue. The FTC noted that "there is strong evidence that agreements not to compete with an authorized generic have become a way for brand-name companies to compensate generic competitors for delaying entry. These agreements can be part of 'pay-for-delay' patent settlements, which have long concerned the Commission." *See id*. at vi. The FTC found that an authorized generic can cut a first-filer's generic revenue by more than half during the first 180 days of generic marketing, and forces generic prices down. *Id.* at iii, vi, 41-48, 57-59.

61. A 2006 study sponsored by the brand drug company trade association, PhRMA, similarly found that an authorized generic results in lower generic prices. A no-authorized generic agreement between a brand and generic drug company—horizontal competitors—injures consumers

[3] *Available at* 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 (last accessed June 7, 2015).

twice: first by prolonging the period during which only the high priced brand is available, and then by ensuring that generic prices are artificially inflated when generic competition finally begins because of the absence of the authorized generic.

62. For an initial generic manufacturer (like Watson) of a branded product (like Lidoderm), the difference between selling the only generic product and competing against an authorized generic for the first months of generic marketing can amount to a payment of hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry, and the FTC's authorized generic report cites numerous documents from industry participants confirming the financial impact of an authorized generic.

63. A no-authorized generic promise, like the one Endo and Teikoku made as payment in exchange for Watson's promise to delay introduction of generic Lidoderm, thus allow horizontal competitors to benefit from an agreement not to compete and denies end-payor purchasers the significantly reduced prices that should flow to them from increased competition.

VI. FACTUAL ALLEGATIONS

A. Background

1. Approval of Brand Lidoderm and the Relevant Patents

64. Lidoderm is a prescription lidocaine-containing pain patch used to treat pain associated with post-herpetic neuralgia (also referred to as after-shingles pain). The active ingredient in Lidoderm is 5% lidocaine. While other drugs may be used to treat the same or similar conditions, they are not AB-rated to Lidoderm, cannot be automatically substituted for Lidoderm by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Lidoderm, and thus are not economic substitutes for, nor reasonably interchangeable with, Lidoderm.

a. Initial Approval of Lidoderm

65. On May 31, 1996, Hind Health Care, Inc. submitted NDA 20-612 to the FDA for marketing approval of an adhesive 5% lidocaine patch for the treatment of pain associated with post-herpetic neuralgia under the brand name Lidoderm. In November 1998, while Hind's application was pending, Hind, Endo, and Teikoku entered into a series of agreements related to Lidoderm. Under those agreements, Hind granted Endo an exclusive license to market and distribute Lidoderm in the

United States, as well as an exclusive license to patents related to Lidoderm. Teikoku was designated as the manufacturer and supplier of Lidoderm. Endo and Teikoku entered into a separate supply and manufacture agreement.

66. On March 19, 1999, the FDA approved Hind's Lidoderm NDA. After gaining FDA approval, Hind transferred the ownership of the Lidoderm NDA to Teikoku Pharma. Endo launched Lidoderm in the United States in 1999.

b. Endo and Teikoku Acquire Lidoderm Patents

67. Endo and Teikoku owned or obtained assignments of or licenses to a number of patents associated with Lidoderm. As of January 2010 (when Watson filed the first ANDA as to Lidoderm), Teikoku had three Lidoderm-related patents listed in the Orange Book. By agreement with Teikoku, Endo had the sole and exclusive right to institute, prosecute, and control any lawsuits alleging infringement of any Orange Book-listed patents covering Lidoderm, and Teikoku was required to assign any such infringement claims to Endo.

68. U.S. Patent Nos. 5,411,738 (the "'738 patent") and 5,601,838 ("the '838 patent") were originally assigned to Hind and were licensed to Endo as part of the November 1998 agreements. The '738 patent is a method of use patent for treating certain types of pain with lidocaine using a topical delivery mechanism and a gel formulation of lidocaine. The '838 patent is a method of use patent for treating certain types of pain with lidocaine. Both patents, collectively referred to as the "Hind patents," expired on May 2, 2012.

69. The third patent listed in the Orange Book as covering Lidoderm was U.S. Patent No. 5,827,529 (the "'529 patent"). The '529 patent, titled "External Preparation for Application to the Skin Containing Lidocaine," is a formulation patent for a lidocaine patch. This patent was assigned to Teikoku on October 27, 1998, and is set to expire on October 27, 2015. Endo is the exclusive licensee of the '529 patent.

70. The '529 patent originated from an application filed on June 10, 1994, which was a continuation of an application filed on March 30, 1992. The '529 patent claims foreign priority to Japanese Application No. 3-067353, filed March 30, 1991. Its priority date is March 30, 1991.

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

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

c. Endo and Teikoku Acquire Additional Patents

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

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

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

76. Teikoku then submitted the ’510 patent to the FDA for listing in the Orange Book with respect to Lidoderm.

77. In May 2011, in exchange for $2 million, Endo acquired from LecTec full title to the ’263 patent, the ’510 patent and three other patents. The three other patents were: U.S. Patent No. 6,096,333 (the “’333 patent”); U.S. Patent No. 6,096,334 (the “’334 patent”); and U.S. Patent No. 6,361,790 (the “’790 patent”) (collectively with the ’263 and the ’510 patents, “the Rolf patents,” named for one of the inventors). These three patents all expired on March 30, 2014, and cover methods

of formulating a medicinal adhesive patch. Other than the '510 patent, none of the Rolf patents has been listed in the Orange Book with respect to Lidoderm.

2. Watson's ANDA Threatens Endo and Teikoku's Patents

78. On November 13, 2009, Watson submitted ANDA 200675 to the FDA for approval of a generic version of Lidoderm. On or about January 14, 2010, Watson notified Teikoku of its ANDA filing. At this point the only patents listed in the Orange Book as covering Lidoderm were the '738, '838, and '529 patents. Watson's notice letter included a Paragraph IV certification that the commercial manufacture, use and/or sale of its generic Lidoderm product would not infringe any claim of the '529 patent and that the '529 patent was invalid and/or unenforceable. Watson was the first generic manufacturer to file an ANDA with a Paragraph IV certification with respect to Lidoderm, potentially entitling it to a six-month exclusivity period free from competition from any other ANDA-filing generic company. This exclusivity, however, would not have protected Watson from competition from an authorized generic version of Lidoderm.

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

80. Watson made no certification as to any of the Rolf patents because, as of January 2010, the Rolf patents were not listed in the Orange Book. Because the Rolf patents were not listed in the Orange Book, they were not an impediment to Watson's launch of its approved generic Lidoderm product.

81. FDA granted final approval of Watson's ANDA on August 23, 2012. Because of the unlawful Agreement with Endo and Teikoku, however, Watson did not launch its approved generic Lidoderm product until September 15, 2013.

B. <u>The Patent Litigation Against Watson Exposes the Weaknesses of Endo and Teikoku's Patents</u>

82. On February 19, 2010, shortly after Watson notified Teikoku of its Lidoderm ANDA filing, Endo and Teikoku filed suit against Watson in the United States District Court for the District of Delaware, *Endo Pharm. Inc. v. Watson Lab.* 10-cv-00138-GMS, alleging that Watson's generic

Lidoderm product would infringe the '529 patent (the "'529 Litigation"). As a result of the filing of the '529 Litigation, a 30-month Hatch-Waxman stay applied to Watson's ANDA, which precluded the FDA from approving Watson's ANDA until (i) that stay expired in July 2012 or (ii) entry of a final judgment that the '529 patent was invalid, unenforceable, and/or not infringed, whichever came first. Watson raised several defenses, including that the '529 patent was invalid and/or unenforceable.

83. Endo filed a second suit against Watson on June 29, 2011, in the United States District Court for the District of Delaware, *Endo Pharm. Inc. v. Watson Lab.* 11-cv-00575-GMS (the "Rolf Patent Litigation"). This suit alleged that Watson's generic Lidoderm product would infringe three of the Rolf patents (the '333,'334, and'510 patents). Endo did not allege that Watson's product would infringe the other two Rolf patents (the '263 and '790 patents). Of the five Rolf patents, only the '510 patent had been listed in the Orange Book. The FDA determined, however, that the '510 patent was late-listed with respect to Watson's ANDA and thus Watson was not required to submit a Paragraph IV certification as to the '510 patent. Because the Rolf patents had not been listed in the Orange Book when Watson filed its ANDA, the Rolf Patent Litigation did not result in a 30-month Hatch-Waxman stay.

1. The '529 Litigation

84. In the '529 Litigation, Endo and Teikoku alleged that Watson's generic product would infringe the '529 patent. Watson denied the allegations, and counterclaimed for declaratory relief that the '529 patent was invalid and unenforceable, and that Watson's generic product would not infringe the '529 patent even if it was valid.

85. Throughout the '529 Litigation, Watson made compelling arguments that the '529 patent was invalid and would not be infringed by Watson's generic product. Watson argued that the '529 patent was obvious in light of prior art, including Endo and Teikoku's own patents, and that the terms of the '529 patent did not cover Watson's generic product. On June 27, 2011, the district court issued a claims construction ruling in which it adopted Watson's construction of the terms of the '529 patent, thereby strengthening Watson's defense to Endo and Teikoku's infringement claims.

86. The '529 Litigation proceeded to a six day bench trial in February 2012, in which Watson presented evidence of the invalidity of the '529 patent, as well as evidence that Watson's

generic did not infringe the patent. The evidence at trial exposed the '529 patent to a determination that it was invalid or unenforceable and that the patent did not cover either the brand product or Watson's generic product. After the trial concluded, the parties submitted post-trial briefs.

87. Before the district court entered any substantive post-trial rulings, Endo, Teikoku, and Watson filed a joint stipulation on June 1, 2012 announcing that they had settled the '529 Litigation and requesting dismissal of the action without prejudice. The district court entered the stipulation on June 13, 2012.

a. The '529 Patent Was Invalid

88. The evidence developed during the '529 Litigation revealed that the same hydrogel transdermal patch technology claimed in the '529 patent had previously been disclosed in multiple pieces of prior art that were not disclosed to the patent examiner, but that were well known to Endo and/or Teikoku (the "Teikoku Prior Art"). The Teikoku Prior Art disclosed a hydrogel transdermal patch formulation substantially similar to that claimed in the '529 patent, except for the active pharmaceutical ingredient.

89. Each piece of the Teikoku Prior Art discloses an "adhesive gel base" consisting of (i) a water-soluble high molecular weight substance; (ii) water; and (iii) a water-retaining agent, all of which fall within the percentage ranges claimed in the '529 patent. Each shares at least one inventor with the '529 patent, and Teikoku is the applicant or assignee for each patent.

90. During the prosecution of the '529 patent, the PTO rejected the patent at least four times noting that because lidocaine was conventionally used in transdermal patches, it would have been obvious to place lidocaine into the Teikoku Prior Art patches. The applicants consistently distinguished other prior art patches cited by the Examiner, arguing that the patch in the '529 patent was "unique." The applicants never disclosed the Teikoku Prior Art to the PTO, or a prior art patent with the same elements as the '529 patent, which would have disclosed that the patch technology in the '529 patent was not unique, and in fact had been previously patented. The PTO did not cite the Teikoku Prior Art.

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

and thus invalidates the '529 patent. Thus, the '529 patent was not capable of preventing Watson from launching its approved generic Lidoderm product.

b. The '529 Patent Was Not Infringed

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

93. In the '529 patent, the first Markush group related to "a water-soluble high molecular weight substance selected from the group consisting of gelatin, starch, agar, mannan, alginic acid, polyacrylic acid, a salt of polyacrylic acid, dextrin, methylcellulose, methylcellulose sodium, carboxymethylcellulose, carboxymethylcellulose sodium, polyvinyl alcohol, polyvinyl pyrrolidone, copolymer of methyl vinyl ether and maleic anhydride, gum arabic, tragacanth, karaya gum and locust bean gum."

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

95. The parties submitted claim construction briefing on the interpretation of these terms. Relying on Federal Circuit precedent from 2003, the district court adopted Watson's interpretation and held that both of the relevant Markush groups in the '529 patent were limited to one and only one of the listed alternatives. *Endo Pharm., Inc. et al., v. Watson Lab., Inc.,* slip op. at 1 n.1-2.

96. Both Lidoderm and Watson's generic Lidoderm product contain at least four water-soluble high molecular weight substances, and three water-retaining agents. Thus, they are outside the

scope of the ’529 patent because they each contain more than one substance from each Markush group. As a result, Watson’s generic Lidoderm product does not infringe the ’529 patent.

2. The Rolf Patent Litigation

97. The Rolf patents at issue in the second litigation (the ’333, ’334, and ’510 patents) also afforded Endo and Teikoku no basis to prevent Watson from launching its approved generic Lidoderm product. Watson had raised defenses and counterclaims alleging those patents were invalid and/or unenforceable and that its product did not infringe them. The Rolf Patent Litigation barely proceeded past the pleading stage before the parties entered into the Agreement and brought an end to the litigation. The Rolf patents posed no reasonable risk to Watson of patent infringement liability.

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

99. And, Endo argued in the LecTec Litigation that the ’510 patent was subject to a strong challenge as being invalid as obvious in view of prior art references that were not submitted to the PTO during the prosecution of the ’510 patent.

100. Watson was aware of the infirmities of the ’510 patent from the publicly filed pleadings in the LecTec Litigation. The ’510 patent was incapable of preventing Watson from launching its generic Lidoderm product upon the FDA’s approval of Watson’s ANDA.

101. The ’333 and ’334 patents were also not infringed by Watson. In fact, during the LecTec litigation, LecTec had not even sued Endo for infringement of the ’333 and ’334 patents with respect to Lidoderm. And when Endo ultimately settled the LecTec Litigation in November 2009, it obtained licenses only to the ’263 and ’510 patents. In fact, Endo did not obtain the rights to the ’333 and ’334 patents until May 2011 when it purchased all of the Rolf patents. Watson’s generic patch – which is therapeutically equivalent to Lidoderm – similarly would not infringe the ’333 and ’334 patents.

C. Endo’s Strategic Filing of a Citizen’s Petition

102. On March 12, 2012 – after the February 2012 bench trial in the ‘529 Litigation, and more than two years after Watson filed its ANDA – Endo filed a citizen petition requesting that the FDA take

fourteen specific actions with regard to lidocaine patch 5% generics. The 2012 petition was filed as an amendment to two prior petitions filed in December 2006 and August 2007.

103. On August 23, 2012, FDA denied Endo's citizen's petition in its entirety and approved Watson's ANDA.

D. Endo and Teikoku Enter the Unlawful "Pay for Delay" Agreement with Watson

104. On or about May 28, 2012, Endo and Teikoku entered into an agreement with Watson ending the companies' patent litigations related to Lidoderm. The Agreement resolved the litigations as to the '529 patent and all of the Rolf patents. Watson received a license for the '529 patent and all of the Rolf patents (including those that were not at issue in the Rolf Patent Litigation).

105. Under the Agreement, Watson Laboratories, Inc., on behalf of itself and its affiliates, including its parent company, Watson Pharmaceuticals, Inc., agreed that it, and its affiliates, would delay launching its generic Lidoderm product until September 15, 2013, unless otherwise specifically authorized by the Agreement. The Agreement specifically provides that:

> Watson agrees, on behalf of itself and its Affiliates, that, prior to the Start Date, it and its Affiliates shall not directly or indirectly market, offer to sell, sell, have sold, import, manufacture or have manufactured in the Territory any of Watson's Generic Product. Watson acknowledges and agrees that each of Endo and Teikoku would be irreparably harmed should Watson breach this Section…. [Agreement, Section 2(e).]
>
> ****
>
> "Start Date" means the earliest of: (i) September 15, 2013; (ii) the date of Launch of any Generic Product other than Watson's Generic Product; or (iii) the last day before Watson would forfeit its 180-day generic drug 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).]

106. As the *quid pro quo* for Watson's promise to delay entry of its generic Lidoderm product until September 15, 2013, Endo and Teikoku agreed to pay Watson by: (1) providing at least $96 million worth of branded Lidoderm at no cost to Watson, leaving Watson free to sell and retain the full proceeds of those sales; and (2) agreeing not to launch an authorized generic product for at least 7½ months, so long as Watson was the sole generic Lidoderm product on the market.

1. Payment Of at Least $96 Million

107. From January 1, 2013 through August 1, 2013, Endo and/or Teikoku were to provide Watson with branded Lidoderm worth $12 million each month, for a total of at least $96 million worth of branded Lidoderm. Watson was free to sell the product on its own and retain the full proceeds of those sales. This payment was no different than if Endo and Teikoku had paid Watson at least $96 million in cash. The Agreement specifically provides:

> Endo/Teikoku shall provide, at no cost, to Watson's Wholesaler Affiliate Brand Product of value totaling twelve million dollars ($12,000,000) per month, as measured at the time of each delivery by the then-prevailing Wholesale Acquisition Cost as defined in the Red Book or, if the Red Book is not available, any other comparable U.S. price listing ("WAC"), on the first business day of each month beginning January 1, 2013 and ending August 1, 2013 (for a total of eight (8) months) for Watson's Wholesaler Affiliate's disposal as provided in Section 3(e). Endo shall provide to Watson's Wholesaler Affiliate an invoice with respect to such Brand Product, which invoice shall reflect the transfer of Brand Product to Watson's Wholesaler Affiliate at no cost. Notwithstanding the foregoing, Endo/Teikoku's obligations under this Section 3(b) shall terminate immediately upon the Launch of any Third Party Generic Product in the Territory. The Brand Product provided to Watson's Wholesaler Affiliate by Endo/Teikoku shall have the same NDC number as the Brand Product sold by Endo. [Agreement, Section 3(b)(emphasis added).]

108. Endo and Teikoku also agreed to make additional payments to Watson by providing more branded product if Watson did not receive FDA approval for its generic Lidoderm product by January 1, 2014, and further payments if Watson did not receive approval by January 1, 2015. Neither situation came to pass; Watson received final FDA approval on August 23, 2012.

109. The compensation to Watson under the Agreement far exceeded Endo and Teikoku's avoided litigation costs and, as the Agreement acknowledged, was payment for the settlement of the litigation and independent of any other transaction:

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

110. The terms of the Agreement ensured that Watson's Lidoderm sales would not result in price competition, but instead that Watson would sell brand Lidoderm at the same supracompetitive

prices at which Endo had been selling it. The Agreement required Watson to honor all of Endo's price-related contracts with its wholesalers:

> 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 Territory on pricing and other terms determined by Watson's Wholesaler Affiliate in its sole discretion, provided that neither Watson nor any of its Affiliates (including its Wholesaler Affiliate) shall sell, distribute or dispose of Branded Product in any manner that would constitute a Bundled Sale. Watson agrees that its Wholesaler Affiliate will honor all Endo price related contracts as communicated to all Endo wholesalers from time to time in the ordinary course of business, provided that the price related contracts do not impose any requirements on Watson's Wholesaler Affiliate that would be inconsistent with requirements imposed upon other Lidoderm® wholesalers, and further provided that such price-related contracts shall not conflict with the terms of this Agreement. [Agreement, Section 3(c) (emphasis added).]

111. Instead of Watson releasing its generic product before September 2013, Endo, Teikoku, and Watson agreed to split Endo's monopoly profits that branded Lidoderm generated. Watson's sales of branded Lidoderm did not increase output, reduce price, or increase consumer choice; it merely substituted Watson for Endo as the seller of $96 million worth of branded Lidoderm, solely to pay Watson for delaying market entry of its less-expensive generic Lidoderm.

2. No-Authorized Generic Promise

112. Endo also agreed to delay launching an authorized generic for up to 7½ months after Watson launched its generic product, so long as Watson was the sole generic Lidoderm product on the market. The Agreement (which refers to an authorized generic by the acronym "AG") provides:

> License. Subject to the terms and conditions of this Agreement, Endo/Teikoku hereby grant to Watson a non-exclusive (other than pursuant to Section 2(b)), royalty-bearing, non-transferable (other than pursuant to Section 21) and non-sublicensable (other than pursuant to Section 2(c)) license to the Licensed Patents to make, have made, import, use, sell, and offer for sale Watson's Generic product in the Territory solely during the License Term. [Agreement, Section 2(a).]
>
> *****
>
> AG Product. The license granted pursuant to Section 2(a) shall be partially exclusive for a period of time in that Endo/Teikoku and their respective Affiliates shall not market or sell a Generic Product, or authorize or license a Third Party to market or sell an AG Product at any time before the earlier of (i) seven and a half (7.5) months from the Start Date, and (ii) the Launch of any Third Party Generic Product in the Territory. [Agreement, Section 2(b) (emphasis added).]

113. Endo was otherwise ready, willing, and able to launch an authorized generic version of Lidoderm simultaneously with Watson's entry. As early as April 2007, Endo and Teikoku had specifically agreed that Endo would be the exclusive licensee for authorized generic Lidoderm. Watson had no intellectual property covering authorized generic versions of Lidoderm that would have prevented Endo from launching an authorized generic product. In fact, following the expiration of the no-authorized generic promise an authorized generic was launched.

114. As shown below, the no-authorized generic promise turned out to have a cash value to Watson of $150 million or more. Endo's agreement not to launch an authorized generic meant that Watson would be the sole generic on the market for up to 7½ months, so long as no other ANDA filer obtained FDA approval and entered the market. Watson could therefore expect to maintain a supracompetitive generic price, obtain all generic sales, and earn higher profits than it otherwise would have earned, all at the expense of Plaintiffs and members of the Class.

115. Endo sacrificed profit (which it would have shared with Teikoku) by its agreement not to launch an authorized generic. Absent the unlawful Agreement, it would have been in Endo and Teikoku's economic interest for Endo to launch an authorized generic once Watson launched its generic product, so that Endo and Teikoku could retain some of the sales that Watson's less expensive generic otherwise would capture. As alleged above, an authorized generic product typically captures approximately 50% of the generic sales during the first 180 days of generic marketing. Thus, the no-authorized generic provision constituted a very large payment from Endo and Teikoku to Watson.

116. As is common in the pharmaceutical industry, the first generic is expected to take a significant majority of the brand sales within six months. That is what happened here. During the 7½ months of Watson's generic exclusivity, during which time Endo did not launch an authorized generic pursuant to the Agreement, Watson generated gross profits of over $400 million from generic sales. Pursuant to the 25% royalty provision in the Agreement, Watson paid approximately $100 million in royalties to Endo based on gross profits. The effect was that Watson enjoyed over $300 million in profits net of royalties during that time period.

117. Watson's expectations would have differed dramatically if Endo had not promised to refrain from competing with its own authorized generic. As is common in the industry, when there is

one generic on the market, it is typically priced at 90% of the brand. According to an FDA study of the dynamics of generic competition, the addition of a second generic drives the average generic price down to as low as 52% of the brand price. Thus, if the generics would still take the same percentage of brand sales, the total generic *revenues* would drop by approximately 42.2% (1.00 – 0.52/0.90 = .422). Total generic *profits*, therefore, would have also dropped by 42.2% or more. Further, if Endo had not agreed to concede the generic market to Watson, it would be reasonable to expect that generic sales would have been split evenly between Watson and Endo's authorized generic (though there is reason to expect that the brand might have enjoyed a marketing advantage as the incumbent and garner more than 50% of sales). Based on these estimates, absent the no-authorized generic agreement, Watson would have expected to receive less than half of the revenue it actually obtained from generic Lidoderm and substantially less than half of the $300 million it actually enjoyed in gross profits net of royalties.

118. Thus, Endo's agreement not to launch an authorized generic for 7½ months constituted a payment to Watson of $150 million or more. The value of this Agreement to Watson was no different as a practical matter than if Endo and Teikoku had handed $150 million in cash (their respective portions of the proceeds of the authorized generic sales) to Watson.

3. The Reverse Payments Were Large and Unjustified

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

120. Absent Endo and Teikoku's unlawful payments to Watson, Watson would have launched much earlier than September 2013, either through an agreement that did not include a payment and permitted an earlier entry date or by entering the market "at risk" after final approval but

prior to the resolution of the patent litigation. In either event, Endo and Teikoku would have launched an authorized generic concurrently with, or shortly after, Watson launched its generic version of Lidoderm.

121. Endo and Teikoku used the power of direct financial remuneration, as opposed to the strength of their patents, to obtain the agreement of Watson not to launch its generic Lidoderm product until September of 2013. Given the risk of an unfavorable ruling in the '529 patent litigation—which would have eliminated Endo's monopoly over Lidoderm and swiftly eradicated the vast majority of its Lidoderm sales—Endo and Teikoku agreed to share the money they received from Endo's monopoly with Watson as the *quid pro quo* for Watson's agreement not to compete with Endo in the lidocaine patch 5% market until September 15, 2013.

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

E. Anticompetitive Purpose and Effect of Defendants' Conduct

123. This unlawful Agreement between horizontal competitors not to compete and allocate the market has enabled Defendants to: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patch 5% in the United States; (b) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products, even after generic entry; (d) allocate 100% of the United States lidocaine patch 5% market to Endo for up to 13 months; and (e) allocate 100% of the United States lidocaine patch 5% market to Watson for up to 7½ months.[4]

[4] Plaintiffs previously deleted paragraph 123 of the Amended Complaint (ECF No. 72) alleging *per se* illegality of the agreement to withhold an authorized generic in light of the Court's Order Granting in Part and Denying in Part Motion to Dismiss (ECF No. 117, at 26-27, November 17, 2014). Plaintiffs

124. But for the unlawful Agreement: (i) Watson would have begun selling its generic version of Lidoderm when or shortly after it received FDA approval on August 23, 2012, which was after the expiration of the 30-month stay that arose out of the '529 Litigation; (ii) Endo would have launched an authorized generic lidocaine patch 5% to compete with Watson's generic product; and (iii) an increasingly competitive market for lidocaine patch 5% would have emerged and prices for both the branded and generic products would have declined rapidly and significantly.

125. Starting in late 2011, Watson represented to Wall Street analysts that it was pursuing its ANDA, that it was closely monitoring the progress of the ANDA and expected approval in 2012, that its efforts to increase capacity were well underway, and that it expected to be "ready to go at the earliest possible time to launch the product." Watson continued to make these representations to analysts through early 2012.

126. Watson would have launched its generic product despite any patents that Endo or Teikoku may have claimed covered Lidoderm, and prior to resolution of any litigation over the '529 or Rolf patents. Given the defects in these patents, Watson would have launched upon final FDA approval even in the absence of a court ruling on those patents. Once Watson obtained FDA approval of its ANDA, it was free to launch, and Watson would have launched its generic Lidoderm immediately. Furthermore, none of the patents other than the '529 patent discussed above were listed in the Orange Book when Watson filed its ANDA. Thus, Watson was not required to certify to those patents under Hatch-Waxman, and the Rolf Patent Litigation would not, and could not, result in a 30 month Hatch-Waxman stay of FDA approval of Watson's ANDA. The 30-month stay that arose out of the '529 Litigation had already expired by the time Watson's ANDA was approved.

127. Alternatively, but for the unlawful Agreement: (i) Endo, Teikoku and Watson would have entered into a procompetitive settlement agreement under which Watson would have entered the market much earlier than September 2013 and Endo and Teikoku would not have paid Watson for delay; (ii) Endo would have launched its authorized generic lidocaine patch 5% coincident with the

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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.

launch of Watson's generic product; and (iii) an increasingly competitive market for lidocaine patch 5% would have emerged.

128. Defendants' unlawful actions have delayed the sale of generic Lidoderm in the United States, and unlawfully enabled Endo and Watson to fix prices and to sell lidocaine patch 5% at artificially inflated, supracompetitive prices. But for Defendants' illegal conduct, generic competition to Lidoderm would have begun prior to September 15, 2013, and would have included both Endo's authorized generic and Watson's generic Lidoderm product.

VII. INTERSTATE AND INTRASTATE COMMERCE

129. At all material times, Teikoku manufactured and Endo promoted, distributed, and sold substantial amounts of Lidoderm (and Watson manufactured, promoted, distributed, and sold substantial amounts of generic Lidoderm) in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States. Beginning in September 2013 Watson manufactured, promoted, distributed, and sold substantial amounts of generic Lidoderm in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

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

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

132. Defendants' anticompetitive conduct has had substantial intrastate effects in that, among other things, retailers within each state did not have access to less expensive generic Lidoderm that they could sell to end-payors within each respective state. The delay of generic Lidoderm, including Endo's authorized generic product, has directly impacted and disrupted commerce for end-payors within each state.

133. During the relevant time period, Lidoderm was shipped into each state and was sold to or paid for by end-payors. Beginning in September 2013, an AB-rated generic version of Lidoderm was shipped into each state and sold to or paid for by end-payors.

134. Defendants' conduct as alleged herein had substantial effects on intrastate commerce in each state because Lidoderm was sold to consumers and third-party payors in each state and Defendants entered into an unlawful, anticompetitive Agreement that affected commerce in each state.

VIII. MARKET POWER AND MARKET DEFINITION

135. At all relevant times, Endo possessed market power over lidocaine patch 5% because it had the power to maintain lidocaine patch 5% prices at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Lidoderm and its AB-rated generic equivalents.

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

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

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

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

140. Endo possessed, and exercised, the power to exclude and restrict competition to Lidoderm and its AB-rated generics.

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

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

143. Plaintiffs allege that the relevant market is lidocaine patch 5% (*i.e.*, Lidoderm and its AB-rated generic equivalents). During the relevant period, Endo was able to profitably maintain the price of lidocaine patch 5% well above competitive levels.

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

145. At all relevant times, Defendants' market share in the relevant market was and is 100%, demonstrating substantial market power.

IX. EFFECTS ON COMPETITION, AND DAMAGES

146. Defendants' unlawful Agreement has delayed generic competition, unlawfully enabled Endo to sell branded Lidoderm without generic competition, and allowed Watson to sell generic Lidoderm with competition from an authorized generic.

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

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

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

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

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

152. But for Defendants' unlawful Agreement, there would have been greater competition in the market for lidocaine patch 5%. End-payors like Plaintiffs and other members of the Class would have paid less for lidocaine patch 5% by (a) substituting purchases of less-expensive AB-rated generic Lidoderm for their purchases of more-expensive branded Lidoderm, (b) receiving discounts on their remaining branded Lidoderm purchases, and (c) purchasing generic Lidoderm at lower prices sooner. As a result of Defendants' illegal conduct as alleged herein, Plaintiffs and other Class members were compelled to pay, and did pay, artificially inflated prices for their lidocaine patch 5% requirements.

153. During the relevant period, Plaintiffs and other Class members have purchased substantial amounts of Lidoderm indirectly from Endo and substantial amounts of generic Lidoderm indirectly from Watson. Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

X. ANTITRUST IMPACT

154. Supracompetitive prices for pharmaceuticals at a higher level of distribution generally result in higher prices at every level below. This case is no exception.

155. Wholesalers and retailers passed on the supracompetitive prices of branded Lidoderm and AB-rated generic Lidoderm to Plaintiffs and Class members.

156. Defendants' anticompetitive conduct enabled them to indirectly raise, fix, and stabilize prices to consumers and third-party payors in excess of the prices Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

157. The supracompetitive prices paid by Plaintiffs and Class members are traceable to, and the direct, proximate and foreseeable result of, Defendants' supracompetitive prices.

158. General economic theory recognizes that any overcharges in the form of supracompetitive prices at a higher level of distribution in the chain of distribution for Lidoderm results in higher prices at every level below. Herbert Hovenkamp, *Federal Antitrust Policy, the Law of Competition and Its Practice* 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

159. Defendants' anticompetitive conduct enabled them to raise, fix, and stabilize prices to consumers and third-party payors in excess of what consumers and third-party payors otherwise would paid absent Defendants' anticompetitive conduct.

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

161. The overcharges the members of the Classes paid are traceable to, and the foreseeable result of, the supracompetitive prices that were raised, fixed, and stabilized by Defendants.

XI. CLAIMS FOR RELIEF

CLAIM I: CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(Asserted against All Defendants)

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

163. This claim is pled as to all Defendants.

164. In or about May 2012, and at times prior to the formal execution thereof, Defendants entered into the Agreement. The Agreement is an illegal contract, combination and conspiracy in restraint of trade under which Endo and Teikoku agreed to make large, unjustified reverse payments to Watson in exchange for Watson's agreement to delay bringing its generic version of Lidoderm to the market, the purpose and effect of which were to: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patch 5% in the United States; (b) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly

earlier time; (c) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products, even after generic entry; (d) allocate 100% of the United States lidocaine patch 5% market to Endo for up to 13 months; and (e) allocate 100% of the United States lidocaine patch 5% market to Watson for up to 7½ months.

165. Defendants thus implemented the terms of the Agreement and achieved its intended purpose. As a direct and proximate result of Defendants' anticompetitive conduct, as alleged herein, Plaintiffs and the Class were harmed as set forth above.

166. The Agreement covered a sufficiently substantial percentage of the relevant market so as to harm competition.

167. There was and is no legitimate, non-pretextual, procompetitive justification for the reverse payment from Endo and Teikoku to Watson that outweighs its harmful effect. Even if there were some conceivable justification, the reverse payment was not necessary to achieve that purpose.

168. By engaging in the foregoing conduct, Defendants entered a conspiracy and combination in restraint of trade in violation of the following state laws[5]:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 16720, *et seq.*, with respect to purchases in Arizona, California, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia by members of the Class and/or purchases by California residents.

c. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class and/or purchases by Florida residents.

d. Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Class and/or purchases by Kansas residents.

[5] Plaintiffs have deleted all state law statutory claims dismissed by the court in its Order Granting in Part and Denying in Part Motion Dismiss (ECF No. 117, pp. 33-35, 38-44 and 46-49) and Order Granting in Part and Denying in Part Defendants' Motion to Dismiss Second Amended Complaints (ECF No. 179, pp. 2-3). Plaintiffs preserve all rights with respect to these claims, including appellate rights and the right to amend their Complaint to re-allege these claims.

e. Me. Rev. Stat. Ann. 10 § 1101, *et seq.*, with respect to purchases in Maine by members of the Class and/or purchases by Maine residents.

f. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class and/or purchases by Massachusetts residents, with thousands of Massachusetts end-payors paying substantially higher prices for Lidoderm and its generic equivalents in actions and transactions occurring substantially within Massachusetts.

g. Minn. Stat. §§ 325D.51, *et seq.*, with respect to purchases in Minnesota by members of the Class and/or purchases by Minnesota residents.

h. Nev. Rev. Stat. Ann. § 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class and/or purchases by Nevada residents, in that thousands of sales of Lidoderm and its AB-rated generic equivalents took place at Nevada pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

i. N.H. Rev. Stat. Ann. §§ 356:2, *et seq.*, with respect to purchases in New Hampshire by members of the Class and/or purchases by New Hampshire residents.

j. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class and/or purchases by New Mexico residents.

k. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class and/or purchases by New York residents.

l. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class and/or purchases by North Carolina residents.

m. N.D. Cent. Code § 51-08.1-02, *et seq.*, with respect to purchases in North Dakota by members of the Class and/or purchases by North Dakota residents.

n. S.D. Codified Laws Ann. § 37-1-3.1, *et seq.*, with respect to purchases in South Dakota by members of the Class and/or purchases by South Dakota residents.

o. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class and/or purchases by Tennessee residents, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Lidoderm and AB-rated generic equivalents at Tennessee pharmacies.

p. W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Class and/or purchases by West Virginia residents.

q. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Lidoderm and AB-rated generic equivalents in Wisconsin by members of the Class and/or purchases by Wisconsin residents, in that the actions and transactions alleged herein substantially

affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Lidoderm and AB-rated generic equivalents at Wisconsin pharmacies.

169. Plaintiffs and Class members have been (and will continue to be) injured in their business or property by reason of Defendants' violations of laws set forth above, in that Plaintiffs and Class members (i) were denied the opportunity to purchase lower-priced generic Lidoderm, and (ii) paid higher prices for branded Lidoderm than they would have paid but for the unlawful conduct. These injuries are of the type the laws of the above-listed jurisdictions were designed to prevent and flow from that which makes the conduct unlawful.

170. Plaintiffs and Class members seek damages and multiple damages as permitted by law for their injuries.

Compliance With The Written Demand Requirement of Mass. Gen. Laws Ann. Chapter 93A

171. The demand letter requirement of Section 9 of Massachusetts General Laws Annotated Chapter 93A does not apply because no Defendant has identified a place of business or assets within Massachusetts. In an abundance of caution, however, Plaintiff Letizia Gallotto, individually and on behalf of all others similarly situated, served each Defendant with a written demand for relief pursuant to Mass. Gen. Laws Ann., Chapter 93A, section 9, on April 22, 2015, more than 30 days before the filing of this Complaint. The demand identified the claimant as Ms. Gallotto, stated that Ms. Gallotto seeks relief on behalf of herself and all those similarly situated in the Commonwealth of Massachusetts, reasonably described the unfair or deceptive act or practice alleged (the Agreement among Defendants to delay the marketing of Watson's generic version of Lidoderm), described the injury suffered (the payment of higher costs for lidocaine patch 5%), and set forth a demand for relief (offer of settlement based on the supracompetitive prices paid by purchasers of Lidoderm such as Plaintiff Gallotto, who produced her purchase data to Defendants during discovery). Plaintiff Gallotto alleges that the written demand for relief satisfies the statute's purpose of encouraging negotiation and settlement. The Endo and Actavis Defendants responded to Plaintiff Gallotto's demand letter, but have not provided a written tender of settlement. The Teikoku Defendants have not submitted a response to Plaintiff Gallotto's demand letter.

CLAIM II: CONSPIRACY TO MONOPOLIZE UNDER STATE LAW
(Asserted against All Defendants)

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

173. This claim is pled as to all Defendants.

174. 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.

175. Through the unlawful Agreement alleged herein Endo and Teikoku conspired with Watson to maintain Endo's monopoly power in the relevant market in order to block and delay market entry of generic lidocaine patch 5%, *i.e.*, AB-rated generic versions of Lidoderm. The unlawful Agreement (a) allocated 100% of the market for lidocaine patch 5% in the United States to Endo; (b) delayed the availability of generic Lidoderm products; and (c) fixed the price at which Plaintiffs and members of the Class would pay for lidocaine patch 5% at the higher, branded price.

176. The goal, purpose and/or effect of the unlawful Agreement was to maintain and extend Endo's monopoly power in the United States market for lidocaine patch 5%. The Agreement prevented and/or delayed generic competition to Lidoderm and enabled Endo to continue charging supracompetitive prices for Lidoderm without a substantial loss of sales.

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

178. Defendants specifically intended that the unlawful Agreement would maintain Endo's monopoly power in the relevant market, and injured Plaintiffs and the Class thereby.

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

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

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

182. By engaging in the foregoing conduct, Defendants intentionally, willfully, and wrongfully engaged in a conspiracy to monopolize the relevant market in violation of the following state laws[6]:

a. Arizona Rev. Stat. §§ 44-1402, *et seq.*, with respect to purchases in Arizona by members of the Class and/or purchases by Arizona residents.

b. Cal. Bus. and Prof. Code §§ 16720, *et seq*., with respect to purchases in Arizona, California, Florida, Hawaii, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia by members of the Class and/or purchases by California residents.

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases in Florida by members of the Class and/or purchases by Florida residents.

d. Kan. Stat. Ann. §§ 50-101, *et seq*., with respect to purchases in Kansas by members of the Class and/or purchases by Kansas residents.

e. Me. Rev. Stat. Ann. 10 § 1102, *et seq*., with respect to purchases in Maine by members of the Class and/or purchases by Maine residents.

f. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases in Massachusetts by members of the Class and/or purchases by Massachusetts residents, with thousands of Massachusetts end-payors paying substantially higher prices for Lidoderm and its AB-rated generic equivalents in actions and transactions occurring substantially within Massachusetts.[7]

g. Minn. Stat. §§ 325D.54, *et seq*., with respect to purchases in Minnesota by members of the Class and/or purchases by Minnesota residents.

h. Nev. Rev. Stat. Ann. § 598A.060, *et seq*., with respect to purchases in Nevada by members of the Class and/or purchases by Nevada residents, in that thousands of sales of Lidoderm and its AB-rated generic equivalents took place at Nevada

[6] Plaintiffs have deleted all state law statutory claims dismissed by the court in its Order Granting in Part and Denying in Part Motion Dismiss (ECF No. 117, pp. 33-35, 38-44 and 46-49) and Order Granting in Part and Denying in Part Defendants' Motion to Dismiss Second Amended Complaints (ECF No. 179, pp. 2-3). Plaintiffs preserve all rights with respect to these claims, including appellate rights and the right to amend their Complaint to re-allege these claims.

[7] Although not necessary, Plaintiff Letizia Galloto has complied with the written demand requirement of Mass. Ann. Laws, Chapter 93A, section 9. Please refer to paragraphs 171, 172.

pharmacies, purchased by Nevada end-payors at supracompetitive prices caused by Defendants' conduct.

i. N.H. Rev. Stat. Ann. §§ 356:2, *et. seq*., with respect to purchases in New Hampshire by members of the Class and/or purchases by New Hampshire residents.

j. N.M. Stat. Ann. §§ 57-1-2, *et seq*., with respect to purchases in New Mexico by members of the Class and/or purchases by New Mexico residents.

k. New York General Business Law § 340, *et seq*., with respect to purchases in New York by members of the Class and/or purchases by New York residents.

l. N.C. Gen. Stat. §§ 75-2.1, *et seq*., with respect to purchases in North Carolina by members of the Class and/or purchases by North Carolina residents.

m. N.D. Cent. Code § 51-08.1-02, *et seq*., with respect to purchases in North Dakota by members of the Class and/or purchases by North Dakota residents.

n. S.D. Codified Laws Ann. § 37-1-3.2, *et seq*., with respect to purchases in South Dakota by members of the Class and/or purchases by South Dakota residents.

o. Tenn. Code Ann. §§ 47-25-101, *et seq*., with respect to purchases in Tennessee by members of the Class and/or purchases by Tennessee residents, in that the actions and transactions alleged herein substantially affected Tennessee, with thousands of end-payors in Tennessee paying substantially higher prices for Lidoderm and AB-rated generic equivalents at Tennessee pharmacies.

p. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class and/or purchases by West Virginia residents.

q. Wis. Stat. § 133.03, *et seq.*, with respect to purchases of Lidoderm and AB-rated generic equivalents in Wisconsin by members of the Class and/or purchases by Wisconsin residents, in that the actions and transactions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher price for Lidoderm and AB-rated generic equivalents at Wisconsin pharmacies.

183. Plaintiffs and Class members have been (and will continue to be) injured in their business or property by reason of Defendants' violations of law set forth above, in that Plaintiffs and Class members (i) were denied the opportunity to purchase lower-priced generic Lidoderm, and (ii) paid higher prices for branded Lidoderm than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above the above-listed jurisdictions were designed to prevent and flow from that which makes the conduct unlawful.

184. Plaintiffs and Class members seek damages and multiple damages as permitted by law for their injuries.

CLAIM III: VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW
(Asserted Against All Defendants)

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

186. This claim is pled as to all Defendants.

187. By engaging in the conduct set forth above, Defendants engaged in unlawful and unfair business acts or practices in violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §17200, *et seq*.

188. Defendants entered into an Agreement that was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patch 5% in the United States; (b) delay the introduction of an authorized generic lidocaine patch 5%, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain or stabilize the prices of lidocaine patch 5% products, even after generic entry; (d) allocate 100% of the United States lidocaine patch 5% market to Endo for up to 13 months; and (e) allocate 100% of the United States lidocaine patch 5% market to Watson for up to 7½ months.

189. Defendants' conduct constitutes an unfair business practice in that the Agreement is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers in the form of supracompetitive prices. There are no countervailing benefits to consumers, and any utility of Defendants' conduct is outweighed by the consequences to Plaintiffs and other members of the Class.

190. Defendants' conduct also constitutes an unlawful business practice in that it violates:

a. The Cartwright Act, California Business and Professions Code, section 16720, *et seq.*;

b. Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2; and

c. Section 16600 of the California Business and Professions Code, which prohibits "every contract by which anyone is restrained from engaging in a lawful profession, trade, or business of any kind."

191. As a direct and proximate result of Defendants' conduct, Plaintiffs and Class members were deprived of the opportunity to purchase a generic version of Lidoderm and were overcharged and forced to pay higher prices for Lidoderm and generic versions of Lidoderm.

192. As a direct and proximate cause of Defendants' unfair and unlawful business practices as alleged herein, Plaintiffs and members of the Class have suffered injury in fact and lost money and property. They paid higher prices for Lidoderm and/or its AB-rated bioequivalents than they would have paid in the absence of Defendants' unfair and unlawful conduct. This injury is of the type that California's Unfair Competition Law was designed to prevent and directly results from Defendants' conduct.

193. Accordingly, Plaintiffs seek class-wide equitable relief in the form of judicial declarations, restitution and disgorgement as set forth below.

XII. DEMAND FOR JUDGMENT

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

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

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

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

D. Grant Plaintiffs and the Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' illegal conduct, including:

i. A judicial determination declaring the rights of Plaintiffs and Class members, and the corresponding responsibilities of Defendants;

ii. A declaration that Defendants are to be financially responsible for the costs and expenses of a Court-approved notice program by mail, broadcast media, and publication designed to give immediate notification to Class members;

iii. Disgorgement and/or the imposition of a constructive trust upon Defendants' ill-gotten gains, thereby freezing Defendants' assets, and/or requiring Defendants to pay restitution to Plaintiffs and all members of the Class of all funds acquired by means of any act or practice declared by this Court to be an unlawful or unfair business practice, a violation of federal or state statutes, or to constitute unfair competition; and

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

XIII. JURY DEMAND

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

DATED: June 18, 2015

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/s/ Dena C. Sharp

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