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1314151617	FOR THE NORTHERN DI	TES DISTRICT COURT STRICT OF CALIFORNIA SCO DIVISION
18 19 20	THE STATE OF CALIFORNIA, EX REL. XAVIER BECERRA, ATTORNEY GENERAL, Plaintiff,	Case No. 17-cv-00562 COMPLAINT FOR VIOLATIONS OF THE SHERMAN ACT, CARTWRIGHT ACT, AND CALIFORNIA UNFAIR COMPETITION LAW FOR INJUNCTIVE
2122232425262728	WATSON LABORATORIES, INC., now a subsidiary of TEVA PHARMACEUTICAL INDUSTRIES LTD., ALLERGAN FINANCE LLC f/k/a WATSON PHARMACEUTICALS, INC. and ACTAVIS, INC., and ALLERGAN PLC f/k/a ACTAVIS, INC. and ACTAVIS, PLC, Defendants.	RELIEF, DISGORGEMENT AND CIVIL PENALTIES

Complaint of the State of California

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COMES NOW, the State of California ("the State"), ex rel. Xavier Becerra, Attorney General, and alleges the following:

NATURE OF THE CASE

- 1. The State, by and through its Attorney General acting in his official capacity as the State's chief law enforcement officer, brings this action in its sovereign and law enforcement capacities against the generic drug divisions of Watson Laboratories, Inc. (now a subsidiary of Teva Pharmaceutical Industries Ltd., Inc.), Allergan Finance LLC (f/k/a Watson Pharmaceuticals, Inc. and Actavis, Inc.), and Allergan plc (f/k/a Actavis plc) (collectively "Defendants" or "Watson" or "Watson entities"). This action is necessitated by the Watson Defendants' violations of the Sherman Act, the Cartwright Act, and the California Unfair Competition Law by entering into a reverse-payment agreement (a/k/a pay-for-delay agreement) for the purpose and effect of obstructing generic competition to Lidoderm (hereinafter "Agreement" or "Lidoderm Agreement"). This anticompetitive Lidoderm Agreement was between Watson, on the one hand, and the branded drug company Endo Pharmaceuticals Inc., its parent company Endo International plc (f/k/a/ Endo Health Solutions Inc.) (collectively "Endo"), Endo's patent licensor Teikoku Pharma USA, Inc., and its parent company Teikoku Seiyaku Co., Ltd. (collectively "Teikoku"), on the other. The Lidoderm Agreement ensured that Endo would not face generic competition for Lidoderm from Watson from May 2012 through September 2013 and thereafter, Watson would not face generic competition from Endo or Teikoku until May 2014. As a result, consumers were forced to pay hundreds of millions of dollars in supra-competitive prices to fill their prescriptions for Lidoderm and its AB-rated generic equivalents from at least May 2012 through May 2014.
- The relevant market is the United States market for lidocaine patches (i.e., Lidoderm 2. and its AB-rated generic equivalents).
- Lidoderm is the brand-name for lidocaine patches, which is a transdermal patch that is widely used as a local anesthetic to prevent pain and is widely prescribed for relief of pain associated with post-herpetic neuralgia ("PHN"), a common complication of shingles. According to the United States Center for Disease Control, about 33% of the US population will develop shingles in their lifetime, and that risk increases after the age of 50. Children also can develop

shingles, but it is less common. Lidoderm is a preferred pain medication for PHN.

- 4. Lidoderm was developed by Hind Health Care ("Hind") in the 1990s for topical use associated with shingles. In March 1996, Hind submitted a New Drug Application ("NDA") for Lidoderm to the United States Food and Drug Administration ("FDA"). After Hind's Lidoderm formula was patented in 1998 but before its NDA was approved by the FDA, Hind granted Endo an exclusive marketing and distribution license to Lidoderm and also transferred full ownership and responsibility of Lidoderm to Teikoku. In November 1998, Teikoku entered into a supply and manufacturing agreement with Endo and granted Endo the exclusive right to sell Lidoderm in the United States. Throughout the relevant time period, Teikoku manufactured all of the Lidoderm patches that Endo sold in the United States.
- 5. At the time of the Lidoderm Agreement, Lidoderm was Endo's most important branded prescription drug product. In 2011, Endo generated more than \$825 million from its branded Lidoderm patches, comprising 30% of Endo's total annual revenues. The threat of generic entry to Lidoderm posed significant financial risks for the company. Endo knew that generic competition would decimate its Lidoderm sales and that any delay in generic competition would be highly profitable for Endo, but very costly for consumers.
- 6. Two and a half years before entering into the Lidoderm Agreement with Endo and Teikoku, Watson had submitted an Abbreviated NDA ("ANDA") to the FDA for approval of a generic version of Lidoderm. In January 2010, Watson notified both Endo and Teikoku of its ANDA. In February 2010, shortly after receiving Watson's ANDA notice, Endo and Teikoku sued Watson for patent infringement. Thereafter, Endo acquired three additional Lidoderm patents and based thereon filed a second suit against Watson in June 2011 for infringement of those patents.
- 7. As to Endo and Teikoku's first patent infringement suit, the district court issued a claims construction ruling on June 27, 2011 adopting Watson's construction of the Lidoderm patent at issue. A six-day bench trial ensued in February 2012.
- 8. Thus, by 2012, generic entry appeared imminent and indeed, Watson publicly stated that it was preparing to launch its generic as early as the middle of 2012.

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- 9. Upon completion of the trial on Endo and Teikoku's first patent suit, Watson, Endo and Teikoku all submitted post-trial briefs. But before the district judge entered any substantive rulings on those briefs, Endo and Teikoku bought off Watson and settled both patent infringement suits filed against Watson. Their settlement agreement, i.e., the Lidoderm Agreement, was executed on May 28, 2012.
- 10. Under the terms of the Lidoderm Agreement, Endo paid Watson to not compete with Endo's lucrative Lidoderm franchise. Thus, as part of the Agreement, the Watson entities agreed to abandon the patent challenges and forgo entry with a lower-cost generic version of Lidoderm for more than a year, until September 2013. Endo and Teikoku agreed to make payments to Watson under the Lidoderm Agreement having two components. First, Endo and Teikoku agreed to provide Watson Pharma with branded Lidoderm patches "at no cost" from January 2013 through August 2013, which Watson Pharma's wholly-owned distribution subsidiary, Anda, Inc., could sell for pure profit. The so-called free branded Lidoderm products are valued at \$96 million to \$240 million. Second, Endo and Teikoku guaranteed that Watson would receive supracompetitive profits by being the only seller of generic Lidoderm during at least the first 180 days—and up to the first 7½ months—on the market, i.e., from September 2013 through May 2014. Even though Endo had the legal right and financial incentive to sell an authorized generic version of Lidoderm as soon as Watson entered with its generic product, Endo agreed to refrain from competing on generic Lidoderm for up to the first 7½ months of Watson's generic sales. This "no-AG commitment" was worth hundreds of millions of dollars to Watson. In total, Endo and Teikoku's payment to the Watson entities was worth at least \$250 million.
- 11. In August 2012, the FDA granted Watson final approval to launch its generic lidocaine patches. But pursuant to the Lidoderm Agreement, Watson did not launch its generic Lidoderm product until more than a year later, in September 2013.
- 12. The Defendants' Lidoderm Agreement was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patches in the United States; (b) delay the introduction of an authorized generic lidocaine patch, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the

prices of lidocaine patches, even after generic entry, (d) allocate 100% of the United States market of lidocaine patches to Endo and Teikoku for up to 13 months; and (e) allocate 100% of the United States market of generic lidocaine patches to Watson for up to 7½ months.

- 13. But for the 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. Not only has the Defendants' unlawful Agreement harmed and continues to harm the State's general economy by obstructing generic competition to Lidoderm, it also denied Californians the ability to fulfill their lidocaine patch needs at significantly lower prices far earlier than they did, instead of being forced to pay for branded and generic Lidoderm at supra-competitive prices.
- 14. The Defendants' anticompetitive conduct violates Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1, the Cartwright Act and California's Unfair Competition Law. It is squarely within the State's sovereign interests to ensure the continued enforcement of the antitrust laws and prevent antitrust violations in order to secure a competitive marketplace and the economic well-being of its citizens. Under the Cartwright Act and Unfair Competition Law, the Attorney General need not show irreparable injury to obtain injunctive relief. Cal. Bus. & Prof. Code §§ 16754-54.5.
- 15. Anticompetitive agreements such as the Defendants' Lidoderm Agreement lead consumers, payors and the State to pay, directly or indirectly, monopoly prices for Lidoderm medications and deny them the lower prices that generic competition provides.
- 16. Competition and consumer welfare being the ultimate touchstone of California's antitrust laws, the State of California therefore seeks a permanent injunction order, disgorgement, civil penalties, and any other equitable relief against the Defendants that this Court deems proper to undo and prevent their unfair methods of competition in entering into and maintaining anticompetitive agreements such as the Lidoderm Agreement. As alleged in this complaint, the Defendants have demonstrated, through their execution and concerted enforcement of the anticompetitive Lidoderm Agreement with Endo and Teikoku and other conduct alleged herein that they remain a serious threat to the states' consumer welfare and competitive marketplaces.
 - 17. During the relevant time period through 2011, the Watson Defendants were

California-based companies with headquarters in Corona, California.

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JURISDICTION AND VENUE

- 18. This complaint alleges violations of the Sherman Act, 15 U.S.C. § 1. It is filed under, and jurisdiction is conferred upon this Court by, Sections 12 and 16 of the Clayton Act, 15 U.S.C. §§ 22 and 26. The Plaintiff also alleges violations of California state antitrust, unfair competition and related laws, and seeks civil penalties and/or other equitable relief under those state laws. All claims under federal and state laws are based upon a common nucleus of operative facts, and the entire action commenced by this complaint constitutes a single case that would ordinarily be tried in one judicial proceeding.
- 19. The Court has jurisdiction over the federal claims under 28 U.S.C. §§ 1331 and 1337. The Court has jurisdiction over the state claims under 28 U.S.C. § 1367 under the Court's supplemental jurisdiction because those claims are so related to the federal claims that they form part of the same case or controversy.
- 20. Venue is proper in this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391 because each Defendant resides, transacts business, committed an illegal or tortious act, is found in this District, is otherwise subject to the Court's personal jurisdiction with respect to this action, or a substantial part of the events giving rise to the claims arose in this District.
- 21. The Defendants' activities, as described herein, were within the flow of, were intended to, and did have a substantial effect on the foreign and interstate commerce of the United States.

PLAINTIFF

- 22. Plaintiff is the State of California, ex rel. Xavier Becerra, Attorney General, acting in its sovereign and law enforcement capacities. The State is authorized to bring actions such as this to obtain injunctive relief as a remedy for violations of the Sherman Act. See 15 U.S.C. § 26; Hawaii v. Standard Oil Company of California, 405 U.S. 251, 266, 92 S.Ct. 885, 31 L.Ed.2d 184 (1972).
- 23. As the state's chief law enforcement officer, the Attorney General also is charged with enforcing the state's antitrust laws, including the Cartwright Act (California Business and

Professions Code Sections 16700 – 16770). Under the Cartwright Act, except as provided in the act, "every trust is unlawful, against public policy and void." Cal. Bus. & Prof. Code § 16726. The Attorney General is authorized to bring actions in the name of the People of the State of California under the Cartwright Act to obtain, *inter alia*, disgorgement, and injunctive and other equitable relief to address anticompetitive conduct.

24. The Attorney General is specifically authorized under the Unfair Competition Law, Business and Professions Code Section 17200 to bring actions in the name of the People of the State of California to obtain injunctive, restitution and other equitable relief, and civil penalties to redress unfair, unlawful, and fraudulent business practices. *See* Bus. & Prof. Code §§ 17203, 17204, 17206.

DEFENDANTS

- 25. Defendant Watson Laboratories, Inc. ("Watson Labs") is a for-profit Nevada corporation, having its principal place of business at 575 Chipeta Way, Salt Lake City, Utah 84108. At the time of the Lidoderm Agreement, Watson Labs was engaged in developing, manufacturing, marketing, and distributing branded and generic pharmaceutical products as a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. Through at least late 2011, Watson Labs had its principal place of business at 132 Business Center Drive, Corona, California 92880. Sometime in late 2011 or early 2012, Watson Labs moved its headquarters to Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, partially in response to a May 2002 consent decree entered into with the FDA, which required Watson Labs to ensure that its Corona, California facility complied with the FDA's Good Manufacturing Practices ("cGMP") regulations. Watson Labs signed the Lidoderm Agreement challenged in this complaint on behalf of the Watson entities. Watson Labs began operating as a subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva") in or around July or August of 2016.
- 26. Defendant Allergan Finance LLC (f/k/a Watson Pharmaceuticals, Inc. and Actavis Inc.) is a for-profit Nevada corporation, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At the time of the Lidoderm Agreement, Allergan Finance LLC was known as Watson Pharmaceuticals, Inc. ("Watson

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Defendant Allergan plc (f/k/a Actavis plc) is a for-profit Ireland corporation, with its 27. corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400. Ireland. Allergan plc was created through an all-stock transaction when Actavis, Inc. purchased Warner Chilcott plc and effected a corporate inversion to change its domicile to Ireland for tax purposes. When this occurred in 2012, ownership interests in Actavis, Inc. were transferred to Allergan plc, and substantially the same management team continued the same business under the newly created entity. According to the Federal Trade Commission ("FTC") There is no indication that Actavis, Inc. was provided any consideration as part of this transaction. Although its corporate headquarters are in Ireland, Allergan plc's operational headquarters are in Parsippany, New Jersey, where Actavis, Inc. was headquartered prior to the creation of Allergan plc. Most—if not all—of Allergan plc's management team live in the New at the New Jersey location, which Allergan York/New Jersey area and work describes in its public filings as the company's "administrative headquarters." Indeed, Allergan is expanding its footprint in New Jersey to further consolidate "key functions of our organization into a single location." Allergan plc is the parent company of Allergan Finance, LLC (formerly Actavis, Inc.). Paul Bisaro, currently Allergan plc's Executive Chairman, approved the Lidoderm agreement at issue in the action on behalf of the Watson entities. In recent years, Allergan plc has exercised control over Allergan Finance LLC—including causing the transfer of many branded and generic pharmaceutical products from Allergan Finance LLC to other Allergan plc

subsidiaries without any known consideration to Allergan Finance LLC—such that Allergan plc and Allergan Finance LLC have a unity of interest. Because transfers of assets such as this could defeat remediation obtained against Allergan Finance LLC, an inequitable result would occur if Allergan plc were found to be separate from Allergan Finance LLC for the purpose of this action.

- 28. Watson Labs, Allergan Finance LLC and Allergan plc are collectively referred to herein as "Defendants" or "Watson" or "Watson entities." The Watson Defendants are engaged in worldwide marketing, production and distribution of generic pharmaceuticals products, including in this judicial district and through its wholly-owned wholesaler affiliates including Anda, Inc.
- 29. The Watson Defendants' actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of Defendants.

CO-CONSPIRATORS

- 30. Endo Pharmaceuticals Inc. is a for-profit Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals is engaged in the business of, among other things, developing, manufacturing, and marketing branded and generic pharmaceutical products. Endo Pharmaceuticals entered into the anticompetitive agreement challenged in this complaint. Endo Pharmaceuticals markets and sells Lidoderm throughout the United States.
- 31. Endo International plc is the parent company to Endo Pharmaceuticals Inc. Endo International is a for-profit Ireland corporation, with its global headquarters at 1st Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and its U.S. headquarters in Malvern, Pennsylvania. Endo International had \$2.9 billion in revenue in 2014. At the time of the anticompetitive agreement challenged in this complaint, Endo Pharmaceuticals Holdings was the parent of Endo Pharmaceuticals Inc., and it was doing business as Endo Health Solutions Inc.

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- Endo Pharmaceuticals and Endo International are collectively referred to herein as 32. "Endo."
- Teikoku Seiyaku Co., Ltd., is the for-profit parent company of Teikoku Pharma USA. 33. Teikoku Seiyaku is a company organized and existing under the laws of Japan, having its principal place of business at 567 Sanbonmatsu, Higashikagawa, Kagawa 769-2695 Japan. Teikoku Seivaku is the assignee of U.S. Patent No. 5,827,529 (the "529 patent"), which was the subject of a patent lawsuit filed by Endo and Teikoku against Watson, as alleged in this complaint. Teikoku manufactures Lidoderm in Japan for commercial sale in the United States exclusively by Endo under a November 1998 Supply and Manufacturing Agreement with Endo. Endo pays Teikoku Seiyaku royalties under that agreement, as amended. Teikoku Seiyaku entered into the anticompetitive agreement challenged in this complaint.
- Teikoku Pharma USA, Inc. is a for-profit 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 New Drug Application for Lidoderm. Teikoku Pharma, through its parent company Teikoku Seiyaku Co., Ltd., is one of the largest pharmaceutical patch manufacturers in the world. Under the Manufacturing and Supply Agreement with Endo, Teikoku Pharma through its operations in San Jose, California supplies Endo with the Lidoderm manufactured by Teikoku Seiyaku for commercial sale exclusively by Endo in the United States. Endo shares its monopoly profits in the branded Lidoderm product with Teikoku Pharma by paying it certain per-unit acquisition costs under that agreement, as amended. Teikoku Pharma also entered into the anticompetitive agreement challenged in this complaint.
- Teikoku Seiyaku and Teikoku Pharma are collectively referred to herein as 35. "Teikoku."
- With respect to all of the conduct alleged in this complaint, at all relevant times Endo 36. and Teikoku acted in concert with Watson to (a) delay and/or preclude the entry of less expensive

generic versions of lidocaine patches in the United States; (b) delay the introduction of an authorized generic lidocaine patch, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the prices of lidocaine patches, even after generic entry, (d) allocate 100% of the United States market of lidocaine patches to Endo and Teikoku for up to 13 months; and (e) allocate 100% of the United States market of generic lidocaine patches to Watson for up to $7\frac{1}{2}$ months.

37. At all relevant times Endo acted in concert with Teikoku. Endo and Teikoku each signed the Lidoderm Agreement with Watson and acted in concert with respect to performance of the Agreement, which refers to Endo and Teikoku collectively in provisions relating to the grant of patent licenses to Watson, the agreement not to launch a competing authorized generic for 7½ months, and the obligation to deliver free branded Lidoderm product to pay Watson.

BACKGROUND

A. Federal law facilitates approval of generic drugs

- 38. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs.
- 39. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs."
- 40. The FDA requires NDA holders to identify any patents that an NDA holder believes reasonably could be asserted against a generic company that makes, uses, or sells a generic version of the branded drug. The NDA holder must submit these patents for listing in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) within 30 days of issuance of the patent. 21 C.F.R. §

- 41. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. Upon showing that the generic drug is therapeutically equivalent to the already-approved branded drug, the generic company may rely on the studies submitted in connection with the already-approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).
- 42. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug also must contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.
- 43. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a "paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug.
- 44. If a company makes a paragraph IV certification, it must notify the patent holder of its certification. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiry; (2) district court resolution of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay.
- 45. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a paragraph IV certification ("first filer") with a period of protection from competition with other ANDA filers. This is referred to as the "180-day exclusivity" or "first-filer exclusivity" period. The Supreme Court observed that the 180-day exclusivity period "can prove valuable, possibly worth several hundred million dollars" to the first filer.
 - 46. A brand drug company can market a generic version of its own branded product at

any time, including during the first filer's exclusivity period. In that case, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. Such generics commonly are known as "authorized generics." An authorized generic is chemically identical to the branded drug, but is sold as a generic product, typically through either the brand company's subsidiary or through a third party.

47. In the absence of generic competition, a brand drug company typically will not undercut the profits on its branded drug by introducing a lower-priced authorized generic version of that drug. When an ANDA filer enters, however, an authorized generic may become attractive to the NDA holder as a means of maintaining some of the revenue it otherwise would lose to the generic competitor.

B. State law encourages substitution of AB-rated generic drugs for branded drugs

- 48. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. Indeed, California's generic drug substitution law encourages and facilitates substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, California's substitution law allows the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Cal. Bus. & Prof. Code § 4073; see also Cal. Gov. Code §§ 14977-14980 and 14982; Cal. Labor Code § 4600.1.
- 49. Other states and the District of Columbia also have similar drug substitution laws. These laws were enacted in part because the pharmaceutical market does not function well. In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding which drug to prescribe. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. But these purchasers have little input over what drug is actually prescribed.

50. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

- 51. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, healthcare plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2015 alone, the Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system \$227 billion.
- 52. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.
- 53. Consumers also benefit from competition between an authorized generic drug and an ANDA-based generic drug. Empirical evidence shows that competition from an authorized generic drug during the first-filer's 180-day exclusivity results, on average, in retail prices that are 4% to 8% lower and wholesale prices that are 7% to 14% lower than prices without authorized generic competition.
- 54. Competition from an authorized generic also typically has a significant financial impact on the first ANDA entrant. An authorized generic typically takes a significant share of the first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity period by an average of 40% to 52%. Thus, if a brand company agrees to refrain from launching

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an authorized generic, it can double the first filer's revenues during the 180-day exclusivity period. This financial impact is well-known in the pharmaceutical industry.

ANTICOMPETITIVE CONDUCT

A. Lidoderm is a highly successful, highly profitable brand-name drug

- 55. Lidocaine is a local anesthetic that prevents pain by blocking the signals at the nerve endings in the skin. The FDA first approved lidocaine for topical use in the early 1950s and has subsequently approved various topical lidocaine products for a number of different uses.
- Lidoderm is a transdermal lidocaine patch indicated for relief of pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles. About 1 in 3 people in the United States will develop shingles in their lifetime, and that risk increases after the age of 50. About 1 out of 5 people with shingles will get PHN. The risk of PHN increases with age. In a minority of patients, shingles damages nerve fibers and skin, causing pain that can last for months or even years. There is no known cure for PHN, but pharmaceutical products may offer temporary relief from PHN pain.
- Lidoderm is the only topical lidocaine patch indicated for the relief of pain associated with PHN and the only lidocaine formulation used as a first-line therapy for PHN pain. Unlike other first-line therapies for this condition (including antiepileptics and tricyclic antidepressants), Lidoderm is applied topically, resulting in minimal systemic absorption and a low risk of systemic side effects, drug-drug interactions, and drug-disease interactions. As a result, Lidoderm can be used as long as necessary, with minimal risk of the user developing a tolerance, dependence, or addiction. For these reasons, Lidoderm is a preferred therapy for treating PHN.
- Hind developed Lidoderm and submitted NDA 20-612 to the FDA for its approval 58. on May 31, 1996. 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. On March 19, 1999, the FDA approved Hind's Lidoderm NDA and thereafter, Hind transferred full ownership of and responsibility of its Lidoderm NDA to Teikoku.

("the Hind Patents") expired on May, 2, 2012. After acquiring Lidoderm, Teikoku amended the NDA by identifying an additional patent, U.S. Patent No. 5,827,529 (the '529 patent), to be listed in the Orange book for Lidoderm. The '529 patent expired on October 17, 2015.

60. Teikoku Pharma USA, Inc. owns the Lidoderm NDA, and its Japanese parent,
Teikoku Seiyaku Co., Ltd (collectively with Teikoku Pharma USA) manufactures Lidoderm.
Under the terms of a November 1998 supply and manufacturing licensing agreement between

Initially, Hind identified two patents in the Lidoderm NDA: U.S. Patent Nos.

5,411,738 ("the '738 patent") and 5,601,838 ("the '838 patent"). Both the '738 and '838 patents

- Under the terms of a November 1998 supply and manufacturing licensing agreement between Endo and Teikoku ("Lidoderm Supply and Manufacturing Agreement"), Endo has the exclusive right to sell Lidoderm in the United States. Lidoderm patches are manufactured in Japan and imported into the United States by Teikoku Pharma USA through its operations in San Jose, California. Endo purchases Lidoderm from Teikoku Pharma USA.
- 61. Endo launched Lidoderm in the United States in September 1999. U.S. sales of Lidoderm grew substantially over time, from \$22.5 million in 2000 to \$947.7 million in 2012. For much of this period, Lidoderm was Endo's best-selling product, accounting for up to 65% of the company's total net revenues.
- 62. In July, 2008, Endo was sued by LecTec Co. for infringing two patents: U.S. Patent Nos. 5,741,510 ("the '510 patent") and 5,536,263 ("the '263 patent"). Endo settled this litigation in 2009, paying \$23 million in exchange for exclusive licenses to use the '263' and '510 patents. One year later, Endo granted Teikoku a sublicense to use the '510 patent, who then submitted it for listing in the Orange Book for Lidoderm. In May, 2011, Endo purchased from LecTec Co. full title to the '510, '263 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).
- 63. As a unique treatment for relieving PHN pain, Lidoderm has been highly profitable for Endo. Before the entry of generic versions of Lidoderm, Endo sold branded Lidoderm at prices far above its costs of obtaining product from Teikoku and any royalties Endo paid relating

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to the product without sacrificing unit sales or revenues. Even acco	ounting for other direct
expenses that Endo allocated to selling and marketing Lidoderm, E	Endo's profit margin or
Lidoderm net sales was substantial, typically ranging between	and .

Endo regularly increased its list price, or wholesale acquisition cost ("WAC"), for 64. Lidoderm without sacrificing unit sales. Between 2008 and 2013, Endo steadily increased its Lidoderm WAC from approximately \$169 to more than \$260 per box of 30 patches. Over that same time period, Endo's unit sales of Lidoderm in the United States remained fairly consistent, fluctuating between approximately 1.5 and 2.0 million boxes quarterly. Endo's ability to significantly increase WAC yet retain unit sales occurred despite the introduction of other products approved to relieve pain associated with PHN during the relevant time period.

B. Potential generic competition threatened Endo's Lidoderm franchise

- Lidoderm's financial success drew the attention of several generic competitors. On November 13, 2009, Watson Labs filed ANDA No. 200-675 seeking approval to market a generic version of Lidoderm. Watson Labs' application to the FDA contained a paragraph IV certification that its generic product did not infringe the 529 patent owned by Teikoku and/or that the '529 patent was invalid or unenforceable. The '529 patent does not cover lidocaine, the active ingredient in Lidoderm, which has been used in medications for more than 50 years. Rather, it covers only certain lidocaine patch formulations containing specified ingredient quantities.
- As to the remaining patents listed in the Orange Book for Lidoderm at the time of ANDA filing, Watson Labs filed what is known as a paragraph III certification representing that it would not sell its generic product in the United States until the Hind patents expired on May 2, 2012. Watson made no certification as to any of the Rolf patents which, as of the time of its ANDA filing, were not listed in the Orange Book.
- Watson Labs was the first generic company to file an ANDA with a paragraph IV 67. certification covering the '529 patent. Watson Labs therefore became eligible for first-filer exclusivity, which could prevent the FDA from approving any other generic versions of Lidoderm until 180 days after Watson began selling its generic product. By delaying Watson's entry, Endo could delay all generic Lidoderm entry.

68. On or about January 14, 2010, Watson Labs notified Teikoku of its paragraph IV certification relating to the '529 patent. Under the amended Lidoderm Supply and Manufacturing Agreement with Teikoku, Endo had the exclusive right to determine whether to sue Watson Labs for infringement, the right to name Teikoku as a party if necessary for the action, and the right, with limited exceptions, to control litigation and settlement of any claims. On February 19, 2010, Endo and Teikoku sued Watson Labs for infringement of the '529 patent in federal district court in Delaware.

- 69. Because Endo and Teikoku sued Watson Labs within 45 days of its paragraph IV notification, an automatic 30-month stay was imposed. This stay prevented the FDA from granting final approval to Watson Labs' ANDA until mid-July 2012, absent an earlier court finding that the product did not infringe the '529 patent or that the '529 patent was invalid or unenforceable.
- 70. While the patent litigation was pending, the Watson entities took significant steps to be ready to launch as soon as the FDA approved the Watson ANDA for generic Lidoderm product, including spending more than \$40 million on a Salt Lake City manufacturing plant where Watson would manufacture the generic patches and purchasing millions of dollars of raw materials needed for the patches. In addition, the Watson entities projected revenues from generic lidocaine patch sales in forecasts and budgets for the period beginning in late 2012 or early 2013.
- 71. Launching Watson's generic Lidoderm product upon FDA approval would likely require an at-risk launch. In addressing that possibility for generic Lidoderm, Watson Pharma's CEO, Paul Bisaro, publicly stated that Watson has "never been shy" about launching at risk and that these launch preparations were not a "bluff," but a genuine commitment to launch a generic Lidoderm product upon FDA approval, even if the patent litigation had not yet concluded:

Just for the record and this is an important point, to demonstrate our commitment to this product we've built onto our facility in Salt Lake. We spent \$40 million and we're buying raw material today [February 2012], so we're spending millions of dollars preparing for this launch. So this is not a bluff; it's true.

72. Endo was closely monitoring the steps Watson was taking to prepare for a generic lidocaine patch launch and Watson's public statements about the likelihood of such a launch.

Endo expected that competition from a generic product would lead to rapid and dramatic declines in the company's Lidoderm revenues. During the first year after generic entry, Endo predicted that its branded Lidoderm revenues would decrease by at least \$500 million. Watson similarly forecasted a sharp decline in branded Lidoderm sales after a generic product entered the market.

- 73. 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. As the Patent Case Management Judicial Guide notes: "The construction of patent claims plays a critical role in nearly every patent case. It is central to evaluation of infringement and validity, and can affect or determine the outcome of other significant issues such as unenforceability, enablement, and remedies."
- 74. Shortly after the adverse claim construction decision, Endo filed a separate federal court action against Watson Labs alleging that its generic product infringed three additional patents that Endo had subsequently acquired—the '510 patent the '333 patent, and the '334 patent. Of these three patents, Endo listed only the '510 patent in the Orange Book. No 30-month stay resulted from this later patent litigation.
- 75. A six-day trial on the '529 patent infringement claims occurred in February 2012. Coming out of that trial, Watson was confident in its litigation position.
- 76. After the trial concluded, the parties submitted post-trial briefs. 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 requested dismissal of the action without prejudice. The district court entered the stipulation on June 13, 2012.
 - C. Endo and Teikoku paid Watson to abandon its patent challenge and refrain from competing until September 2013
- 77. On May 28, 2012, Endo, Teikoku, and Watson settled both Lidoderm patent litigations, entering into the Lidoderm Agreement, before a final decision was issued in either case.

78. The Lidoderm Agreement required (i) Watson to abandon the patent challenge and
(ii) Watson Pharma and all its subsidiaries to refrain from initiating future patent challenges
relating to Lidoderm or from launching any generic version of Lidoderm for more than a year,
until September 15, 2013. In exchange, Endo and Teikoku agreed to pay the Watson entities
through two separate components. First, Endo and Teikoku committed not to sell an authorized
generic version of Lidoderm for up to 7½ months following Watson's launch ("No-AG
Payment"). Second, Endo and Teikoku agreed to provide Watson Pharma's wholly-owned
wholesale distributor, Anda, Inc., with free branded Lidoderm product worth at least \$96 million
in 2013 and the possibility of additional free product worth up to approximately \$240 million
through 2015 ("Free Product Payment").

1. The No-AG Payment

even by prevailing in the patent infringement litigations with Endo and Teikoku.

80. Endo had the legal right and financial incentive to compete with an authorized generic version of Lidoderm as soon as Watson entered with its generic Lidoderm product. Under the Lidoderm Agreement, however, Endo agreed not to compete with an authorized generic version of Lidoderm for 7½ months after September 15, 2013, unless a third party launched a generic Lidoderm product. In exchange, Watson agreed to pay Endo a 25% royalty on the gross profits from Watson's generic Lidoderm sales before entry of a second generic product. The parties characterized the No-AG Payment as a "partially exclusive" license.

Watson could not have obtained the No-AG Payment or the Free Product Payment

- 81. The No-AG Payment was extremely valuable to Watson. Because of eligibility for first-filer exclusivity, the No-AG Payment ensured that Watson would not face generic lidocaine patch competition for at least 180 days—and up to 7½ months—after its launch.
 - 82. A substantial portion of this value from the No-AG Payment directly benefitted

Watson Pharma. When Watson launched generic Lidoderm in September 2013, significant quantities of Watson's generic product were sold through Anda, Inc., Watson Pharma's whollyowned distribution subsidiary.

83. The No-AG Payment was costly to Endo. Before settlement, Endo had been planning to launch an authorized generic if Watson launched at risk. Endo estimated that it would earn \$150 million in authorized generic net revenues during the first year following generic entry.

2. The Free Product Payment

- \$4. As part of the Lidoderm Agreement, Endo and Teikoku also agreed to provide \$12 million worth of branded Lidoderm product monthly from January through August 2013 to Watson Pharma through Anda, Inc. "at no cost". The product—worth a total of \$96 million—was free to Watson: Watson paid Endo and Teikoku nothing for the branded product received under the Lidoderm Agreement. Endo and Teikoku further agreed to provide up to \$144 million more in free branded Lidoderm in 2014 and 2015 if the FDA did not approve Watson's generic Lidoderm application. As stated in the Lidoderm Agreement, Endo and Teikoku provided this free branded product to Watson as "a good-faith, bargained-for-resolution of the claims at issue in the Litigation." Even accounting for Teikoku's contributions of \$5 million, Endo's cost of providing the free branded Lidoderm product to Watson was roughly \$85 million.
- 85. Although the free branded product was provided to Anda, Inc., the true beneficiary was Watson Pharma.
- 86. From at least May 2012 when Endo, Teikoku and Watson entered the Lidoderm Agreement through September 2013, Endo, Teikoku and Watson agreed to split Endo's monopoly profits that branded Lidoderm generated, even though Watson could have released its generic Lidoderm as early as August 23, 2012 when the FDA approved its Lidoderm ANDA.

87. Watson's sales of Endo and Teikoku's branded Lidoderm did not increase output, reduce price, or increase consumer choice; it merely substituted Watson for Endo as the seller of the branded Lidoderm products that Endo and Teikoku provided to Watson solely to pay Watson for delaying market entry of its less-expensive generic Lidoderm.

D. Endo and Teikoku's payment to Watson is large

- 88. The payment to the Watson entities under the Lidoderm Agreement is large. The total value of Endo and Teikoku's expected payment to Watson, including the No-AG Payment and the Free Product Payment and discounting any royalties Watson paid to Endo, was at least \$250 million.
- 89. Endo's commitment to refrain from selling an authorized generic for 7½ months and to forgo the profits from authorized generic sales that it would have made during that period resulted in hundreds of millions in gain for Watson at a substantial cost to Endo and Teikoku. Endo and Teikoku's commitment to refrain from selling an authorized generic would substantially increase Watson's expected generic Lidoderm revenues by allowing Watson to capture all generic Lidoderm sales, instead of splitting these sales with Endo or Teikoku's authorized generic. Additionally, as the only seller of generic Lidoderm, Watson could charge up to 33% more than if it faced competition from an authorized generic. In May 2012—the same month it entered into the Lidoderm Agreement—Watson prepared several forecasts projecting Watson's revenues and profits from generic Lidoderm sales. Based on these forecasts, Watson could expect to earn at least \$214 million more in generic Lidoderm revenues during its first six months on the market if it did not face generic competition from an Endo authorized generic. Extending the effects of the no-AG commitment to the full 7½ months granted under the Lidoderm Agreement increases the value to at least \$260 million.
- 90. The Free Product Payment was worth more than \$90 million in additional compensation to Watson. Watson anticipated that it would sell the free branded product to customers at the prevailing market price, which was approximately 4% to 5% lower than the contemporaneous brand wholesale acquisition cost (commonly referred to as "WAC"). Thus, for the \$96 million of free branded product that Endo and Teikoku would supply to Watson Pharma

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through Anda, Inc. in 2013, Watson Pharma could expect to profit by \$91.2 to \$92 million. Because Watson Pharma did not have any direct costs for the free branded product, its entire revenues from those sales were profit.

- Any royalty Watson paid to Endo on Watsons's generic sales would not offset Endo and Teikoku's payment to Watson. Based on Watson's contemporaneous forecasts, its royalty payments to Endo would only amount to approximately \$101 million, compared to Endo and Teikoku's total payment in excess of \$350 million.
- Endo and Teikoku's payment far exceeds any reasonable measure of avoided 92. litigation costs in the parties' underlying patent litigation. The settlement occurred late in the litigation, after a six-day trial and post-trial briefing. Endo already had spent around \$11.5 million on the litigation while Teikoku had spent around \$2.3 million. Watson's litigation spending was approximately \$6.8 million. Any remaining litigation costs from either Lidoderm patent suit would be a small fraction of Endo and Teikoku's total payment.
- Endo and Teikoku's payment was designed to, and did, induce Watson to abandon the Lidoderm patent challenge and agree to refrain from marketing its generic Lidoderm product until September 2013. Watson's decision to settle was driven not by the strength of Endo and Teikoku's patent protection for Lidoderm, but by the large payment Endo and Teikoku made to Watson.
- Indeed, Endo and Teikoku's payment exceeded Watson's litigation expenses in the parties underlying patent litigation. Moreover, it exceeded the amount Watson projected to earn by launching its generic version of Lidoderm. Based on internal forecasts prepared around the time of settlement, Watson would earn at least \$100 million more from the Lidoderm Agreement payment (even accounting for the royalty payments it would make to Endo) than it would earn by launching generic Lidoderm immediately following FDA approval in 2012.
- Endo and Teikoku were nonetheless willing to make the large payment to Watson because the September 15, 2013 entry date would ensure that Endo could maintain monopoly prices for Lidoderm throughout that period.

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E. Endo and Teikoku's large payment is not justified

- 96. Endo and Teikoku's payment to Watson cannot be justified solely as compensation for services to be performed by Watson. In fact, Watson provided no services to Endo or Teikoku in exchange for the Lidoderm Agreement payment worth hundreds of millions of dollars.
- 97. Providing \$96 million worth of free branded product to Watson Pharma through its wholesale distributor did not result in any significant procompetitive benefits. Indeed, Anda, Inc. sold the free branded product at prices comparable to what customers were paying other distributors of branded Lidoderm.
- 98. The purpose and effect of Endo and Teikoku's large payment was to induce Watson to abandon its patent challenge and agree not to compete with a generic version of Lidoderm until September 15, 2013. Endo and Teikoku's commitment to forgo profitable Lidoderm authorized generic sales for 7½ months and to provide free branded product worth \$96 million to Watson make no economic sense independent of securing Watson's agreement not to market a generic version of Lidoderm until September 15, 2013.
- 99. Likewise, Watson agreed not to compete with its own generic version of Lidoderm until September 2013 only because Endo shared its Lidoderm monopoly profits in the form of the No-AG Payment and the Free Product Payment. Without the large payment, Watson would not have agreed to refrain from competing until September 2013.
- 100. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from the Lidoderm Agreement that outweigh the significant competitive harm caused by eliminating the risk of Watson's generic entry until September 2013.
- 101. Moreover, Endo and Teikoku's payment to Watson was not reasonably necessary to achieve any purported procompetitive objective of the Lidoderm Agreement.

MONOPOLY POWER

A. Endo's monopoly power concerning Lidoderm

102. Endo exercised monopoly power in the relevant market for lidocaine patches approved by the FDA for sale in the United States, through Watson's delayed entry with a generic version of Lidoderm in September 2013. There is substantial evidence of Endo's monopoly

power. Endo and Watson predicted a dramatic decline in the average price of lidocaine patches following generic entry. Additionally, Endo and Watson expected that competition from a generic product would lead to a rapid and dramatic decline in Endo's Lidoderm revenues. For example, Endo predicted that, during the first year after generic entry, its Lidoderm revenues would decrease by at least \$500 million.

- 103. The data available since the entry of Watson's generic version of Lidoderm confirm the unique competitive impact of such entry on Lidoderm sales and prices. When Watson entered with its generic product, Endo reduced the price of branded Lidoderm as much as 40% in an effort to retain lidocaine patch sales. Nonetheless, within three months, Watson's generic product had captured over 70% of the lidocaine patch unit sales.
- 104. If Endo already were facing robust competition to Lidoderm, then the entry of generic competition to Lidoderm would not erode the sales volume of branded Lidoderm or the price of lidocaine patches so rapidly and dramatically.
- 105. In addition, other drugs used to treat PHN have not meaningfully constrained Endo's pricing or sales of Lidoderm. Between 2008 and 2013, Endo steadily increased its Lidoderm WAC from approximately \$169 to \$260 per box of 30 patches. Over that same period, however, Endo's unit sales of Lidoderm in the United States remained largely stable, fluctuating between 1.5 and 2.0 million boxes quarterly. During that same period, the entry of new branded products approved to relieve pain associated with PHN, such as Qutenza, Horizant, and Gralise, had no discernible impact on Lidoderm prices or unit sales.
- 106. Moreover, because of its unique characteristics, Lidoderm is not reasonably interchangeable with other medications used to relieve pain associated with PHN. Unlike other PHN treatments, Lidoderm is a topical treatment that can be used at home and applied directly to the skin on the affected area. While other drug therapies, such as anticonvulsants and antidepressants, may be used in conjunction with lidocaine patches to improve results, they are not viewed by physicians as substitutes. As the head of Endo's Pain Management business explained: "Lidoderm was unique in the attributes that it presents to a physician and to a patient as they're seeking a therapy . . . [T]here really is not another product that is exactly like

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- 107. At all relevant times, Endo, Teikoku and Watson conspired to give Endo monopoly power in the United States market for branded Lidoderm through September 2013.
- 108. At all relevant times, Endo, Teikoku and Watson conspired to give Endo monopoly power in the United States market for branded Lidoderm through September 2013.
- 109. Before September 2013, Endo consistently held a 100% share of the relevant market for branded lidocaine patches.
- 110. Substantial barriers to entry exist in the lidocaine patch market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic lidocaine patches also face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities to manufacture the patches, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

В. Watson's monopoly power concerning generic lidocaine patches

- 111. Watson exercised monopoly power in the relevant market of generic lidocaine patches approved by the FDA for sale in the United States from September 2013 until Endo began selling an authorized generic in May 2014. While numerous other drugs are used to relieve pain associated with PHN (including branded Lidoderm), there is substantial evidence of Watson's monopoly power throughout the relevant time period. Both Endo and Watson predicted that generic lidocaine patch prices would fall considerably upon entry of the second generic product, with no corresponding effect on the price of the branded product.
- 112. The data available since the entry of Endo's authorized generic version of Lidoderm confirm the unique competitive impact of such entry on generic Lidoderm sales and prices. By September 2014, Endo's authorized generic product had captured over 40% of generic lidocaine patch unit sales, and authorized generic competition had lowered the average price of generic lidocaine patches by more than 16%. Endo's efforts to discount the branded product had no comparable effect on generic prices.
 - 113. If Watson were already facing robust competition to its generic lidocaine patch, then

the entry of Endo's authorized generic version of Lidoderm would not erode the sales volume of Watson's generic lidocaine patch or the price of lidocaine patches so rapidly and dramatically.

- 114. In addition, although a branded product is therapeutically equivalent to its generic counterpart, a unique competitive dynamic exists between generics. Typically, retail pharmacies stock the branded product plus one generic version. Thus, while the brand company can expect its product to be available at every pharmacy, generic companies must compete against one another to be a pharmacy's primary generic supplier. Price is the primary mechanism of such competition. Consequently, entry of additional generic competitors drives down the average generic price, often to a fraction of the brand's pre-generic-entry price.
- brand's list price (or WAC). But after the initial generic sales, any correlation between the prices of the branded product and the generic products generally dissipates. Branded prices often rise after generic entry as brand companies extract additional profits from those patients who are not price sensitive and continue to buy the branded product, while generic prices fall as more generic products come to market. The head of Endo's Pain Management business summarized this dynamic as follows: "Nobody considers an average price of brand plus generic because they operate in a different dynamic." Instead, "generic pricing tend[s] to be a function of how many competitive players are there in the generic market."
- 116. Potential sellers of generic lidocaine patches face substantial barriers to entry, including obtaining FDA approval, costly specialized equipment and facilities to manufacture the product, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.
- 117. At all relevant times, Endo, Teikoku Watson conspired to give Watson monopoly power in the United States market for generic Lidoderm from at least September 2013 through May 2014.
- 118. Before May 2014, Watson held a 100% share of the relevant market for generic lidocaine patches.

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INTERSTATE AND INTRASTATE COMMERCE

- 119. At all relevant times, Teikoku manufactured and Endo promoted, distributed, and sold substantial amounts of Lidoderm products in a continuous and uninterrupted flow of commerce across state and national lines in the United States. Beginning in September 2013, Watson manufactured, promoted, distributed, and sold substantial amounts of Lidoderm products in a continuous and uninterrupted flow of commerce across state and national lines in the United States.
- 120. At all relevant 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 lidocaine patches.
- 121. In furtherance of their efforts to monopolize and restrain competition in the market for lidocaine patches, 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, as well a commerce affecting the State of California which ranks among the top 10 largest economy worldwide.
- 122. Defendants' anticompetitive conduct has had substantial effects in that, among other things, doctors, pharmacists, and retailers in California did not have access to less expensive generic Lidoderm that they could prescribe or sell to purchasers. The delay of generic Lidoderm, including Endo and Teikoku's authorized generic product, has directly impacted and disrupted commerce affecting California.
- 123. During the relevant time period, Lidoderm was shipped into California and was sold to or paid for by Californians. Beginning in September 2013, an AB-rated generic version of Lidoderm was shipped into California and was sold to or paid for by Californians.
- 124. Defendants' alleged conduct had substantial effects on intrastate commerce in California because Lidoderm was sold to consumers and third-party payors in California and Defendants entered into an unlawful anticompetitive Agreement that affected the commerce in California.

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HARM TO COMPETITION AND CONSUMER WELFARE IN CALIFORNIA

- The Lidoderm Agreement eliminated the risk of generic competition for more than one vear
- 125. By impeding generic competition, Endo, Teikoku and Watson's conduct denied consumers and other purchasers of Lidoderm access to AB-rated generic versions of Lidoderm that would offer the same therapeutic benefit as branded Lidoderm, but at a lower price.
- 126. The agreement between Endo, Teikoku and Watson precluded Watson from launching a generic version of Lidoderm until September 2013 and harmed competition and consumer welfare in California by eliminating the risk that Watson would have marketed its generic version of Lidoderm before September 2013. Through their agreement, Endo and Teikoku eliminated the potential that: (1) Endo or Teikoku would have agreed to settle the patent litigation on terms that did not compensate Watson, but provided for generic entry earlier than September 2013; or (2) Watson would have otherwise launched its generic Lidoderm before September 2013, whether or not patent litigation was still pending.
- 127. Before the Lidoderm Agreement, Watson was preparing to launch its generic lidocaine patch as early as FDA approval, which it received in August 2012. Watson did not plan to wait until a trial or appeals court decision in patent litigation before launching its generic product. Watson's generic entry would have quickly and significantly reduced Endo's market share, promoted economic efficiency, and led to significant price reductions for lidocaine patches. Indeed, when Watson ultimately launched its generic version of Lidoderm in September 2013, Endo immediately responded by providing bigger discounts to retain Lidoderm's preferred position on certain drug formularies.
- 128. Watson abandoned its generic entry plans because it received a share of Endo's monopoly profits in the form of the No-AG Payment and the Free Product Payment. Without the large payment, Watson would have launched its generic version of Lidoderm prior to September 2013.
- 129. Entry of Watson's generic product would have given consumers the choice between branded Lidoderm and lower-priced generic substitutes for Lidoderm. Many consumers would

 have chosen to purchase the lower-priced generic version instead of higher-priced branded Lidoderm. In its contemporaneous forecasts, Endo predicted its Lidoderm revenues would decrease by at least \$500 million during the first year after generic entry. As a result of this generic competition, consumers would have saved hundreds of millions of dollars. By entering into their anticompetitive agreement, Endo, Teikoku and Watson have shared additional monopoly profits at the expense of consumers.

- 130. Absent an injunction, civil penalties, disgorgement and other equitable relief, there is a cognizable danger that Watson will engage in similar violations causing future harm to competition and consumers. The Watson Defendants knowingly entered into and carried out a collusive anticompetitive scheme to preserve and share Endo's monopoly profits. Each did so conscious of the fact that this agreement would greatly enrich them at the expense of consumers.
- 131. Defendants have the incentive, opportunity, and demonstrated interest to continue to enter other reverse-payment agreements in the future. Endo, Teikoku and Watson each continue to develop and manufacture pharmaceutical products. Defendants are regularly involved in multiple patent litigations relating to different drugs. Any of these existing or future patent litigations provides the incentive and opportunity to enter into another a reverse-payment agreement.
- 132. In addition, Defendants have the demonstrated interest to continue to enter into such agreements in the future. According to the FTC, both Endo and Watson have entered into similar reverse-payment agreements, even after the U.S. Supreme Court's 2013 decision in *FTC. v. Actavis*. The FTC further asserts that these agreements include arrangements in which the payment is in the form of: (1) a business transaction entered at or around the same time as the patent litigation settlement (serving a similar purpose as the Free Branded Payment); or (2) a no-AG commitment in which the brand company commits not to sell an authorized generic product for some period of time.
- 133. Defendants obtained the full benefit of their unlawful agreement concerning Lidoderm. They did not abandon or disavow the Lidoderm Agreement or any other reverse-payment agreement following the Supreme Court's decision in *FTC v. Actavis*, which rejected the

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near automatic immunity for reverse-payment settlements that some courts had erroneously adopted.

В. The Lidoderm No-AG Payment reduced competition for generic lidocaine patches for 7½ months

- 134. The Lidoderm Agreement further harmed competition and consumers by eliminating competition for sales of generic lidocaine patches until May 2014.
- 135. Before the Lidoderm Agreement, Endo and Watson were potential competitors in the sale of generic lidocaine patches. Indeed, Endo's authorized generic was the only potential generic competition to Watson's generic lidocaine patch during the 180-day first-filer exclusivity period for generic Lidoderm. Under the Hatch-Waxman Act, the FDA was prohibited by law from approving any other generic version of Lidoderm until the 180-day exclusivity period had expired or been forfeited. Endo, however, was legally entitled to market an authorized generic version of its own Lidoderm product at any time, including during the first filer's exclusivity period.
- 136. Before the Lidoderm Agreement, Endo was planning to launch an authorized generic as soon as Watson launched its generic lidocaine patch. Under its agreement with Teikoku, Endo had the exclusive right to sell an authorized generic version of Lidoderm in the United States. Endo also had the financial incentive to do so. As soon as Watson entered with its generic product, Endo could sell an authorized generic to compete for sales to generic lidocaine users, while preserving branded Lidoderm sales for the minority of users who were willing to pay more for the branded product. Endo estimated that it could make more than \$150 million in net sales during the first year after generic entry by selling an authorized generic in competition with Watson.
- 137. Under the Lidoderm Agreement, however, Watson acquired an exclusive field-of-use license that prevented Endo from launching an authorized generic until May 2014. By eliminating the potential competition between Endo's authorized generic and Watson's generic version of Lidoderm, this acquisition substantially reduced competition in the market for generic lidocaine patches.

138. As a result of Endo, Teikoku and Watson's conduct, competition between generic
lidocaine patches was delayed for 7½ months until May 2014. Absent Endo and Teikoku's
commitment not to compete with an authorized generic, Endo or Teikoku would have launched
an authorized generic at or near the time of Watson's generic lidocaine patch entry. Endo's
authorized generic entry would have resulted in significantly lower prices for generic lidocaine
patches and hundreds of millions of dollars in savings for generic lidocaine patch purchasers.
Instead, Endo, Teikoku and Watson shared additional profits at the expense of consumers.

- 139. Upon termination of the exclusive field-of-use license, Endo immediately launched a Lidoderm authorized generic through its subsidiary, Qualitest. Competition from Endo's authorized generic product caused the price of generic lidocaine patches to quickly fall by 16% or more. This significant price reduction is consistent with Endo's and Watson's forecasts as well as the empirical literature on the price effects of authorized generic competition.
- 140. The partially exclusive nature of Watson's license resulted in no cognizable benefits to counteract the harm caused by the absence of competition from an authorized generic.
- 141. Endo's commitment not to compete with an authorized generic was not reasonably related to achieving any cognizable benefits of a larger procompetitive venture.
- 142. Because of barriers such as FDA approval, entry by other firms would not occur to deter or counteract the competitive effects of eliminating an authorized generic.

VIOLATIONS ALLEGED

Count I

(Violation of Section 1 of the Sherman Act, 15 U.S.C. § 1)

(Agreement in Restraint of Trade - Against the Watson Defendants)

- 143. The State hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 144. Defendants have engaged in an unlawful contract, combination, or conspiracy that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.
 - 145. In or about May 2012 and at times prior to the formal execution thereof, Defendants

· 28 entered into the Lidoderm Agreement, an unlawful contract, combination or conspiracy to restrain trade that was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patches in the United States; (b) delay the introduction of an authorized generic lidocaine patch, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the prices of lidocaine patches, even after generic entry, (d) allocate 100% of the United States market of lidocaine patches to Endo and Teikoku for up to 13 months; and (e) allocate 100% of the United States market of generic lidocaine patches to Watson for up to $7\frac{1}{2}$ months.

- 146. There is and was no legitimate, non-pretextual, procompetitive justification for the large payment from Endo and Teikoku to Watson that outweighs its harmful effect on competition. Even if there were some such conceivable justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such purpose.
- 147. As a direct and proximate result of Defendants' Agreement in restraint of trade, the State's sovereign and law enforcement interests were harmed.
- 148. The State is therefore entitled to injunctive relief to enjoin Defendants from engaging in similar conduct in the future and to restore competition in its Lidoderm and AB-rated generic equivalent markets. The Defendants have demonstrated, through their concerted enforcement of the anticompetitive agreement challenged in this complaint and other conducted alleged herein, that they remain a serious threat to competition in the State of California. The State is also entitled to its costs of suit, including reasonable attorneys' fees and such other relief as it just and equitable.

Count II

(Violation of Section 2 of the Sherman Act, 15 U.S.C. § 2)

(Conspiracy to Monopolize - Against the Watson Defendants)

- 149. The State hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 150. At all relevant times, Endo possessed substantial market power (i.e., monopoly power) in the branded Lidoderm market in the United States while Watson possessed substantial

 market power in the United States generic Lidoderm market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competition from, the branded Lidoderm market; and Watson possessed the power to control prices in, prevent prices from falling in, and exclude competition from, the generic Lidoderm market.

- 151. Through the Lidoderm Agreement, Endo, Teikoku and Watson conspired to maintain Endo's monopoly power in the branded Lidoderm market in order to delay market entry of generic Lidoderm. Endo, Teikoku and Watson conspired to maintain Watson's monopoly power in the generic Lidoderm market by and through the no-AG provision of their anticompetitive Agreement.
- 152. The Lidoderm Agreement was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patches in the United States; (b) delay the introduction of an authorized generic lidocaine patch, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the prices of lidocaine patches, even after generic entry, (d) allocate 100% of the United States market of lidocaine patches to Endo and Teikoku for up to 13 months; and (e) allocate 100% of the United States market of generic lidocaine patches to Watson for up to $7\frac{1}{2}$ months.
- 153. The goal, purpose and/or effect of the Agreement was to maintain and extend Endo's monopoly power in the United States market for branded lidocaine patches as well as Watson's monopoly power in the United States market for generic lidocaine patches, both in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. The Lidoderm Agreement was intended to and did prevent and/or delay generic competition to Lidoderm and enabled Endo and Teikoku to continue charging supra-competitive prices for Lidoderm without a substantial loss of sales. Likewise, the Lidoderm Agreement also was intended to and did prevent and/or delay generic competition to Lidoderm and enabled Watson to charge supra-competitive prices for generic Lidoderm without a substantial loss of sales.
- 154. Defendants knowingly and intentionally conspired to maintain and enhance Endo's monopoly power in the United States branded Lidoderm market and also Watson's monopoly power in the United States generic Lidoderm market.

- 155. Defendants specifically intended that their Agreement would maintain Endo's monopoly power in the United States market for branded Lidoderm market through September 2013 as well as Watson's monopoly power in the United States market for generic Lidoderm from September 2013 through May 2014.
 - 156. Defendants each committed at least one overt act in furtherance of the conspiracy.
- 157. As a direct and proximate result of Defendants' concerted monopolistic conduct, the State's sovereign and law enforcement interests were harmed.
- 158. The State is therefore entitled to injunctive relief to enjoin Defendants from engaging in similar conduct in the future and to restore competition in its Lidoderm and AB-rated generic equivalent markets. The Defendants have demonstrated, through their concerted enforcement of the anticompetitive agreement challenged in this complaint, entry of similar agreements, and other conduct alleged herein, that they remain a serious threat to competition in the State of California. The State is also entitled to its costs of suit, including reasonable attorneys' fees and such other relief as is just and equitable.

Count III

(Violation of the Cartwright Act, Cal. Bus. & Prof. Code § 16720, et seq.)

(Agreement in Restraint of Trade – Against the Watson Defendants)

- 159. The State hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 160. In or about May 2012 and at times prior to the formal execution thereof, Defendants entered into the Lidoderm Agreement, an unlawful trust, contract, combination or conspiracy to restrain trade that was designed to and did in fact: (a) delay and/or preclude the entry of less expensive generic versions of lidocaine patches in the United States; (b) delay the introduction of an authorized generic lidocaine patch, which otherwise would have appeared on the market at a significantly earlier time; (c) fix, raise, maintain, or stabilize the prices of lidocaine patches, even after generic entry, (d) allocate 100% of the United States market of lidocaine patches to Endo and Teikoku for up to 13 months; and (e) allocate 100% of the United States market of generic lidocaine patches to Watson for up to 7½ months.

- 161. By engaging in the foregoing conduct, Defendants entered a contract, combination or conspiracy in violation of the Cartwright Act, Bus. & Prof. Code § 16720, et seq.
- 162. Defendants are liable for the anticompetitive settlement agreement challenged in this complaint in that the settlement includes limits on Watson's entry into the Lidoderm market; the settlement includes a cash or equivalent financial consideration flowing from Endo and Teikoku to Watson; and that consideration exceeds the value of goods and services other than the delayed entry into the generic Lidoderm market that Watson provided to Endo, and that consideration also exceeds Endo and Teikoku's expected remaining litigation costs absent the Lidoderm Agreement.
- 163. There is and was no legitimate, non-pretextual, procompetitive justification for the large payment from Endo and Teikoku to Watson that outweighs its harmful effect. Even if there were some such conceivable justification, the payment was not necessary to achieve, nor the least restrictive means of achieving, such purpose.
- 164. As a direct and proximate result of Defendants' Agreement in violation of Section 16720 of the California Business and Professions Code, the State's sovereign and law enforcement interests were harmed.
- 165. The State is therefore entitled to injunctive relief and disgorgement to prevent Defendants from engaging in similar conduct in the future and to restore competition in its Lidoderm and AB-rated generic equivalent markets. The Defendants have demonstrated, through their concerted enforcement of the anticompetitive agreement challenged in this complaint and other conduct alleged herein, that they remain a serious threat to competition in the State of California. The State is also entitled to its costs of suit, including reasonable attorneys' fees and such other relief as is just and equitable. *See* Cal. Bus. & Prof. Code § 16750, 16754, and 16754.5

Count IV

(Violation of the Cartwright Act, Cal. Bus. & Prof. Code § 16720, et seq.) (Conspiracy to Monopolize – Against the Watson Defendants)

166. The State hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

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167. At all relevant times, Endo possessed substantial market power (*i.e.*, monopoly power) in the branded Lidoderm market in the United States while Watson possessed substantial market power in the United States generic Lidoderm market. Endo possessed the power to control prices in, prevent prices from falling in, and exclude competition from, the branded Lidoderm market; and Watson possessed the power to control prices in, prevent prices from falling in, and exclude competition from, the generic Lidoderm market.

168. Through the Lidoderm Agreement, Endo, Teikoku and Watson conspired to maintain Endo's monopoly power in the branded Lidoderm market in order to delay market entry of generic Lidoderm. Endo, Teikoku and Watson conspired to maintain Watson's monopoly power in the generic Lidoderm market by and through the no-AG provision of their anticompetitive Agreement.

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

170. The goal, purpose and/or effect of the Agreement was to maintain and extend Endo's monopoly power in the United States market for branded Lidoderm as well as Watson's monopoly power in the United States market for generic Lidoderm, both in violation of the Cartwright Act, Bus. & Prof. Code § 16720, et seq. The Agreement was intended to and did prevent and/or delay generic competition to Lidoderm and enabled Endo and Teikoku to continue charging supra-competitive prices for Lidoderm without a substantial loss of sales. Likewise, the Lidoderm Agreement also was intended to and did prevent and/or delay generic competition to Lidoderm and enabled Watson to charge supra-competitive prices for generic Lidoderm without a substantial loss of sales.

171. Defendants knowingly and intentionally conspired to maintain and enhance Endo's

monopoly power in the relevant market.

- 172. Defendants specifically intended that their Agreement would maintain Endo's monopoly power in the United States market for branded Lidoderm market through September 2013 as well as Watson's monopoly power in the United States market for generic Lidoderm from September 2013 through May 2014.
 - 173. Defendants each committed at least one overt act in furtherance of the conspiracy.
- 174. As a direct and proximate result of Defendants' concerted monopolistic conduct, in violation of Section 16720 of California's Business and Professions Code, the State's sovereign and law enforcement interests were harmed. The State is therefore entitled to injunctive relief and disgorgement to prevent Defendants from engaging in similar conduct in the future and restore competition in its Lidoderm and AB-rated generic equivalent markets. The Defendants have demonstrated, through their concerted enforcement of the anticompetitive agreement challenged in this complaint and other conduct alleged herein, that they remain a serious threat to competition in the State of California. The State is also entitled to its costs of suit, including reasonable attorneys' fees and such other relief as may be just and equitable. See Cal. Bus. & Prof. Code § 16750, 16754, and 16754.5

Count V

(For Violation of the Unfair Competition Law Business & Professions Code Section 17200, et seq. – Against the Watson Defendants)

- 175. The State hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.
- 176. Defendants engaged, and continue to engage, in unlawful, fraudulent or unfair acts or practices, which constitute unfair competition within the meaning of Section 17200 of the Business and Professions Code. Defendants' acts or practices include, but are not limited to, the following:
 - a. Violations of the Cartwright Act, Cal. Bus. & Prof. Code § 16720, et seq.;
 - b. Violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C §§ 1 and 2;
 - c. Violations of Section 5 of the Federal Trade Commission Act; and

d. Violation of 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."

PRAYER FOR RELIEF

The State requests that:

- (A) the Court adjudge and decree that the Lidoderm Agreement constitutes an illegal restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act;
- (B) the Court adjudge and decree that the Defendants' concerted monopolistic conduct, as alleged herein, constitutes a conspiracy to monopolize in violation of Section 2 of the Sherman Act;
- (C) the Court adjudge and decree that the Lidoderm Agreement constitutes an illegal restraint of trade in violation of the Cartwright Act, Sections 16720, et seq., of the Business & Professions Code;
- (D) the Court adjudge and decree that the Defendants' concerted monopolistic conduct, as alleged herein, constitutes a conspiracy to monopolize in violation of the Cartwright Act, Sections 16720, et seq., of the Business & Professions Code;
- (E) that pursuant to the Cartwright Act and Section 16 of the Clayton Act,

 Defendants be permanently enjoined and restrained from committing any acts
 in violation of state or federal antitrust laws, such as the wrongful acts alleged
 herein;
- (F) that Defendants be disgorged of the ill-gotten gains they had obtained as a result of their acts in violation of the Cartwright Act, as alleged herein.
- (G) that pursuant to Business and Professions Code section 17203, Defendants be permanently enjoined from committing any acts of unfair competition in violation of Business and Professions Code section 17200 as alleged in this complaint;

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that pursuant to Business and Professions Code section 17203, the Court make (H) 1 such orders or judgments as may be necessary to prevent the use or 2 employment by Defendants of any act or practice that constitutes unfair 3 competition or as may be necessary to restore to any person in interest any 4 5 money or property that may have been acquired by means of such unfair competition: 6 that pursuant to Business and Professions Code section 17206, the Court assess (I)7 a civil penalty of \$2,500 for each violation of Business and Professions Code 8 section 17200, as proved at trial; 9 that Plaintiff be awarded such other relief as the Court may deem just and 10 (J) proper to redress and prevent recurrence of the alleged violations and to 11 dissipate the anticompetitive effects of the illegal agreement entered into by 12 Defendants; and 13 (K) that Plaintiff be awarded the costs of this action and reasonable attorneys' fees, 14 including costs of investigation. 15 16 JURY TRIAL DEMAND 17 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by 18 jury for all issues so triable. 19 20 Dated: February 3, 2017 Respectfully submitted, 21 XAVIER BECERRA Attorney General of California 22 23 24 25 Deputy Attorney General Attorneys for Plaintiff the State of California 26 27

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