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8 Attorneys for Plaintiff Federal Trade Commission

9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**
11 **SAN FRANCISCO DIVISION**

12 FEDERAL TRADE COMMISSION,

13 Plaintiff,

14 v.

15 ALLERGAN PLC,

16 ALLERGAN FINANCE LLC,

17 WATSON LABORATORIES, INC.,

18 ENDO INTERNATIONAL PLC,

19 and

20 ENDO PHARMACEUTICALS INC.,

21 Defendants.
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Case No. 17-cv-00312

**COMPLAINT FOR INJUNCTIVE AND
OTHER EQUITABLE RELIEF**

COMPLAINT

REDACTED VERSION OF DOCUMENT SOUGHT TO BE SEALED

1 Plaintiff, the Federal Trade Commission (“FTC”), by its designated attorneys, petitions
2 this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent
3 injunction and other equitable relief against Defendants Endo Pharmaceuticals Inc.; Endo
4 International plc; Watson Laboratories, Inc.; Allergan Finance LLC (f/k/a Actavis, Inc., f/k/a
5 Watson Pharmaceuticals, Inc.); and Allergan plc¹; to undo and prevent their unfair methods of
6 competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C.
7 § 45(a), and an acquisition in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

8 I. Nature of the Case

9 1. This antitrust case challenges an anticompetitive reverse-payment agreement
10 between Endo and Watson to obstruct lower-cost generic competition to Lidoderm, Endo’s most
11 important branded prescription drug product. In 2011, Endo generated more than \$825 million
12 from Lidoderm, a lidocaine patch, comprising 30% of Endo’s total annual revenues. The threat
13 of generic entry to Lidoderm posed significant financial risks for the company. Endo knew that
14 generic competition would decimate its Lidoderm sales and that any delay in generic
15 competition would be highly profitable for Endo, but very costly for consumers.

16 2. By 2012, generic entry appeared imminent. Two-and-a-half years earlier, Watson
17 Labs had submitted an application with the U.S. Food and Drug Administration to market a
18 generic version of Lidoderm. Watson Labs asserted that Endo’s Lidoderm patent was invalid,
19 unenforceable, or would not be infringed by Watson Labs’ generic version of Lidoderm. Watson
20 publicly stated that it was preparing to launch its generic as early as the middle of 2012.

21 3. Faced with Watson’s threat to its lucrative Lidoderm franchise, Endo bought off
22 its potential competitor. In May 2012, Endo agreed to pay the Watson entities to abandon the
23 patent challenge and forgo entry with a lower-cost generic version of Lidoderm for more than a
24

25 ¹ For convenience, Endo Pharmaceuticals Inc. and Endo International plc will be collectively
26 referred to in this Complaint as “Endo.” Watson Laboratories, Inc. will be referred to as “Watson
27 Labs.” Allergan Finance LLC, which was known as Watson Pharmaceuticals, Inc. in 2012 when
28 the reverse-payment agreement with Endo was entered, will be referred to as “Watson Pharma.”
Watson Labs, Watson Pharma, and Allergan plc will be collectively referenced as “Watson” or
“the Watson entities.”

1 year, until September 2013. The payment to the Watson entities included two components. First, 2 Endo guaranteed that Watson would receive supra-competitive profits by being the only seller of 3 generic Lidoderm during at least the first 180 days—and up to the first 7½ months—on the 4 market. Even though Endo had the legal right and financial incentive to sell an authorized 5 generic version of Lidoderm as soon as Watson entered with its generic product, Endo agreed to 6 refrain from competing on generic Lidoderm for up to the first 7½ months of Watson’s generic 7 sales. This “no-AG commitment” was worth hundreds of millions of dollars to Watson. Second, 8 Endo agreed to provide Watson Pharma with branded Lidoderm patches valued at \$96 million to 9 \$240 million “at no cost,” which Watson Pharma’s wholly-owned distribution subsidiary, Anda, 10 Inc., could sell for pure profit. In total, Endo’s payment to the Watson entities was worth at least 11 \$250 million.

12 4. The purpose and effect of this anticompetitive agreement was to ensure that Endo 13 would not face generic competition for Lidoderm until September 2013. As a result, patients 14 were denied the opportunity to purchase lower-cost generic versions of Lidoderm, forcing them 15 and other purchasers to pay hundreds of millions of dollars more for this medication.

16 II. Jurisdiction and Venue

17 5. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. 18 §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

19 6. This Court has personal jurisdiction over each Defendant pursuant to 15 U.S.C. 20 § 53(b) and because each Defendant has the requisite constitutional contacts with the United 21 States of America.

22 7. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and 23 (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). Each Defendant resides, 24 transacts business, committed an illegal or tortious act, is found in this District, or is otherwise 25 subject to the Court’s personal jurisdiction with respect to this action.

26 8. Defendants’ general business practices and the unfair methods of competition 27 alleged herein are “in or affecting commerce” within the meaning of Section 5 of the FTC Act, 28 15 U.S.C. § 45, and as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12.

1 14. Defendant Watson Laboratories, Inc. is a for-profit Nevada corporation, having its
2 principal place of business at 575 Chipeta Way, Salt Lake City, Utah 84108. At the time of the
3 anticompetitive agreement challenged in this complaint, Watson Labs was engaged in
4 developing, manufacturing, marketing, and distributing branded and generic pharmaceutical
5 products. Watson Labs signed the anticompetitive agreement concerning Lidoderm challenged in
6 this complaint on behalf of the Watson entities. As of August 2016, Watson Labs is a subsidiary
7 of Teva Pharmaceutical Industries Ltd.

8 15. Defendant Allergan Finance LLC (f/k/a Actavis Inc. and f/k/a Watson
9 Pharmaceuticals, Inc.) is a for-profit Nevada corporation, having its principal place of business at
10 Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. At the time
11 of the anticompetitive agreement challenged in this complaint, Allergan Finance LLC was
12 known as Watson Pharmaceuticals, Inc. and was engaged in developing, manufacturing,
13 marketing, and distributing branded and generic pharmaceutical products, among other things.
14 The corporate officers of Watson Pharma negotiated the anticompetitive agreement, including
15 substantial provisions directly benefitting Watson Pharma, and Watson Pharma's chief legal
16 officer signed the agreement. In this and other ways discussed in this complaint, Watson Pharma
17 was a direct participant in, and beneficiary of, the unlawful conspiracy with Endo.

18 16. Defendant Allergan plc (f/k/a Actavis plc) is a for-profit Ireland corporation, with
19 its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17
20 E400, Ireland. Allergan plc was created through an all-stock transaction when Actavis, Inc.
21 purchased Warner Chilcott plc and effected a corporate inversion to change its domicile to
22 Ireland for tax purposes. When this occurred in 2012, ownership interests in Actavis, Inc. were
23 transferred to Allergan plc, and substantially the same management team continued the same
24 business under the newly created entity. There is no indication that Actavis, Inc. was provided
25 any consideration as part of this transaction. Although its corporate headquarters are in Ireland,
26 Allergan plc's operational headquarters are in Parsippany, New Jersey, where Actavis, Inc. was
27 headquartered prior to the creation of Allergan plc. Most—if not all—of Allergan plc's
28 management team live in the New York/New Jersey area and work [REDACTED] at the

1 New Jersey location, which Allergan describes in its public filings as the company's
2 "administrative headquarters." Indeed, Allergan is expanding its footprint in New Jersey to
3 further consolidate "key functions of our organization into a single location." Allergan plc is the
4 parent company of Allergan Finance, LLC (formerly Actavis, Inc.). Paul Bisaro, currently
5 Allergan plc's Executive Chairman, approved the Lidoderm agreement at issue in the action on
6 behalf of the Watson entities. In recent years, Allergan plc has exercised control over Allergan
7 Finance LLC—including causing the transfer of many branded and generic pharmaceutical
8 products from Allergan Finance LLC to other Allergan plc subsidiaries without any known
9 consideration to Allergan Finance LLC—such that Allergan plc and Allergan Finance LLC have
10 a unity of interest. Because transfers of assets such as this could defeat remediation obtained
11 against Allergan Finance LLC, an inequitable result would occur if Allergan plc were found to
12 be separate from Allergan Finance LLC for the purpose of this action.

13 **IV. Background**

14 **A. Federal law facilitates approval of generic drugs**

15 17. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as
16 amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-
17 Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of
18 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed
19 to facilitate competition from lower-priced generic drugs, while maintaining incentives for
20 pharmaceutical companies to invest in developing new drugs.

21 18. A company seeking to market a new pharmaceutical product must file a New
22 Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating
23 the safety and efficacy of the new product. These NDA-based products generally are referred to
24 as "brand-name drugs" or "branded drugs."

25 19. The FDA requires NDA holders to identify any patents that an NDA holder
26 believes reasonably could be asserted against a generic company that makes, uses, or sells a
27 generic version of the branded drug. The NDA holder must submit these patents for listing in an
28 FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*

1 (commonly known as the Orange Book) within 30 days of issuance of the patent. 21 C.F.R. §
2 314.53.

3 20. A company seeking to market a generic version of a branded drug may file an
4 Abbreviated New Drug Application (“ANDA”) with the FDA. The generic applicant must
5 demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it
6 references and for which it seeks to be a generic substitute. Upon showing that the generic drug
7 is therapeutically equivalent to the already-approved branded drug, the generic company may
8 rely on the studies submitted in connection with the already-approved branded drug’s NDA to
9 establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).

10 21. The FDA assigns a generic drug an “AB” rating if it is therapeutically equivalent
11 to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage
12 form, safety, strength, route of administration, quality, performance characteristics, and intended
13 use. A generic drug also must contain identical amounts of the same active ingredient(s) as the
14 brand-name drug, although its inactive ingredients may vary.

15 22. When a brand-name drug is covered by one or more patents listed in the Orange
16 Book, a company seeking to market a generic version of that drug before the patents expire must
17 make a “paragraph IV certification” in its ANDA certifying that the patents are invalid,
18 unenforceable, and/or will not be infringed by the generic drug.

19 23. If a company makes a paragraph IV certification, it must notify the patent holder
20 of its certification. If the patent holder initiates a patent infringement suit against the company
21 within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA
22 until the earliest of: (1) patent expiry; (2) district court resolution of the patent litigation in favor
23 of the generic company; or (3) the expiration of an automatic 30-month stay.

24 24. The Hatch-Waxman Act provides the first generic company or companies filing
25 an ANDA containing a paragraph IV certification (“first filer”) with a period of protection from
26 competition with other ANDA filers. This is referred to as the “180-day exclusivity” or “first-
27 filer exclusivity” period. The Supreme Court observed that the 180-day exclusivity period “can
28 prove valuable, possibly worth several hundred million dollars” to the first filer.

1 25. A brand drug company can market a generic version of its own branded product at
2 any time, including during the first filer’s exclusivity period. In that case, no ANDA is necessary
3 because the brand company already has approval to sell the drug under its NDA. Such generics
4 commonly are known as “authorized generics.” An authorized generic is chemically identical to
5 the branded drug, but is sold as a generic product, typically through either the brand company’s
6 subsidiary or through a third party.

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

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

14 27. All 50 states and the District of Columbia have drug substitution laws that
15 encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs.
16 When a pharmacist fills a prescription written for a branded drug, these laws allow or require the
17 pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive
18 branded drug, unless a physician directs or the patient requests otherwise.

19 28. State substitution laws were enacted in part because the pharmaceutical market
20 does not function well. In a well-functioning market, a consumer selects and pays for a product
21 after evaluating the product’s price and quality. In the prescription drug market, however, a
22 patient can obtain a prescription drug only if the doctor writes a prescription for that particular
23 drug. The doctor who selects the drug, however, does not pay for it and generally has little
24 incentive to consider price when deciding which drug to prescribe. Instead, the patient, or in
25 most cases a third-party payer such as a public or private health insurer, pays for the drug. But
26 these purchasers have little input over what drug is actually prescribed.

27 29. State substitution laws are designed to correct this market imperfection by shifting
28 the drug selection choice from physicians to pharmacists and patients who have greater financial

1 incentives to make price comparisons.

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

4 30. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating
5 generic competition and generating large savings for patients, healthcare plans, and federal and
6 state governments. The first generic competitor's product is typically offered at a 20% to
7 30% discount to the branded product. Subsequent generic entry creates greater price competition
8 with discounts reaching 85% or more off the brand price. According to a 2010 Congressional
9 Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price
10 of a brand-name drug. In 2015 alone, the Generic Pharmaceutical Association reported that use
11 of generic versions of brand-name drugs saved the U.S. healthcare system \$227 billion.

12 31. Because of these price advantages and cost savings, many third-party payers of
13 prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to
14 encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result
15 of these policies and lower prices, many consumers routinely switch from a branded drug to an
16 AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically
17 capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

18 32. Consumers also benefit from competition between an authorized generic drug and
19 an ANDA-based generic drug. Empirical evidence shows that competition from an authorized
20 generic drug during the first-filer's 180-day exclusivity results, on average, in retail prices that
21 are 4% to 8% lower and wholesale prices that are 7% to 14% lower than prices without
22 authorized generic competition.

23 33. Competition from an authorized generic also typically has a significant financial
24 impact on the first ANDA entrant. An authorized generic typically takes a significant share of the
25 first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity
26 period by an average of 40% to 52%. Thus, if a brand company agrees to refrain from launching
27 an authorized generic, it can double the first filer's revenues during the 180-day exclusivity
28 period. This financial impact is well-known in the pharmaceutical industry.

1 **V. Anticompetitive Conduct**

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

3 34. Lidocaine is a local anesthetic that prevents pain by blocking the signals at the
4 nerve endings in the skin. The FDA first approved lidocaine for topical use in the early 1950s
5 and has subsequently approved various topical lidocaine products for a number of different uses.

6 35. Lidoderm is a transdermal lidocaine patch indicated for relief of pain associated
7 with post-herpetic neuralgia (“PHN”), a complication of shingles. In a minority of patients,
8 shingles damages nerve fibers and skin, causing pain that can last for months or even years.
9 There is no known cure for PHN, but pharmaceutical products may offer temporary relief from
10 PHN pain.

11 36. Lidoderm is the only topical lidocaine patch indicated for the relief of pain
12 associated with PHN and the only lidocaine formulation used as a first-line therapy for PHN
13 pain. Unlike other first-line therapies for this condition (including antiepileptics and tricyclic
14 antidepressants), Lidoderm is applied topically, resulting in minimal systemic absorption and a
15 low risk of systemic side effects, drug-drug interactions, and drug-disease interactions. As a
16 result, Lidoderm can be used as long as necessary, with minimal risk of the user developing a
17 tolerance, dependence, or addiction. For these reasons, Lidoderm is a preferred therapy for
18 treating PHN.

19 37. An application seeking approval for Lidoderm (NDA No. 20-612) was submitted
20 to the FDA in May 1996. The FDA approved Lidoderm in March 1999.

21 38. Teikoku Pharma USA, Inc. owns the Lidoderm NDA, and its Japanese parent,
22 Teikoku Seiyaku Co., Ltd (collectively with Teikoku Pharma USA, “Teikoku”) manufactures
23 Lidoderm. Under the terms of a November 1998 supply and manufacturing licensing agreement
24 between Endo and Teikoku (“Lidoderm Supply and Manufacturing Agreement”), Endo has the
25 exclusive right to sell Lidoderm in the United States. Lidoderm patches are manufactured in
26 Japan and imported into the United States by Teikoku Pharma USA through its operations in San
27 Jose, California. Endo purchases Lidoderm from Teikoku Pharma USA.

1 39. Endo launched Lidoderm in the United States in September 1999. U.S. sales of
2 Lidoderm grew substantially over time, from \$22.5 million in 2000 to \$947.7 million in 2012.
3 For much of this period, Lidoderm was Endo’s best-selling product, accounting for up to 65% of
4 the company’s total net revenues.

5 40. As a unique treatment for relieving PHN pain, Lidoderm has been highly
6 profitable for Endo. Before the entry of generic versions of Lidoderm, Endo sold branded
7 Lidoderm at prices far above its costs of obtaining product from Teikoku and any royalties Endo
8 paid relating to the product without sacrificing unit sales or revenues. Even accounting for other
9 direct expenses that Endo allocated to selling and marketing Lidoderm, Endo’s profit margin on
10 Lidoderm net sales was substantial, typically ranging between [REDACTED] and [REDACTED].

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

18 **B. Potential generic competition threatened Endo’s Lidoderm franchise**

19 42. Lidoderm’s financial success drew the attention of several generic competitors. In
20 November 2009, Watson Labs filed ANDA No. 200-675 seeking approval to market a generic
21 version of Lidoderm. Watson Labs’ application to the FDA contained a paragraph IV
22 certification that its generic product did not infringe U.S. patent No. 5,827,529 (the “’529
23 patent”) and/or that the ’529 patent was invalid or unenforceable. The ’529 patent does not cover
24 lidocaine, the active ingredient in Lidoderm, which has been used in medications for more than
25 50 years. Rather, it covers only certain lidocaine patch formulations containing specified
26 ingredient quantities.

1 43. Teikoku owns the '529 patent, which expired in October 2015. Under an
2 amendment to the Lidoderm Supply and Manufacturing Agreement, Teikoku granted Endo an
3 exclusive license under the patent to sell Lidoderm in the United States.

4 44. As to the remaining patents listed in the Orange Book for Lidoderm at the time of
5 ANDA filing, Watson Labs filed what is known as a paragraph III certification representing that
6 it would not sell its generic product in the United States until those patents expired on May 2,
7 2012.

8 45. Watson Labs was the first generic company to file an ANDA with a paragraph IV
9 certification covering the '529 patent. Watson Labs therefore became eligible for first-filer
10 exclusivity, which could prevent the FDA from approving any other generic versions of
11 Lidoderm until 180 days after Watson began selling its generic product. By delaying Watson's
12 entry, Endo could delay all generic Lidoderm entry.

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

20 47. Because Endo sued Watson Labs within 45 days of its paragraph IV notification,
21 an automatic 30-month stay was imposed. This stay prevented the FDA from granting final
22 approval to Watson Labs' ANDA until mid-July 2012, absent an earlier court finding that the
23 product did not infringe the '529 patent or that the '529 patent was invalid or unenforceable.

24 48. While the patent litigation was pending, the Watson entities took significant steps
25 to be ready to launch as soon as the FDA approved the ANDA for generic Lidoderm product,
26 including spending more than \$40 million on a Salt Lake City manufacturing plant where
27 Watson would manufacture the generic patches and purchasing millions of dollars of raw
28 materials needed for the patches. In addition, the Watson entities projected revenues from

1 generic lidocaine patch sales in forecasts and budgets for the period beginning in late 2012 or
2 early 2013.

3 49. Launching Watson’s generic Lidoderm product upon FDA approval would likely
4 require an at-risk launch. In addressing that possibility for generic Lidoderm, Watson Pharma’s
5 CEO, Paul Bisaro, publicly stated that Watson has “never been shy” about launching at risk and
6 that these launch preparations were not a “bluff,” but a genuine commitment to launch a generic
7 Lidoderm product upon FDA approval, even if the patent litigation had not yet concluded:

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

13 50. Endo was closely monitoring the steps Watson was taking to prepare for a generic
14 lidocaine patch launch and Watson’s public statements about the likelihood of such a launch.
15 Endo expected that competition from a generic product would lead to rapid and dramatic
16 declines in the company’s Lidoderm revenues. During the first year after generic entry, Endo
17 predicted that its branded Lidoderm revenues would decrease by at least \$500 million. Watson
18 similarly forecasted a sharp decline in branded Lidoderm sales after a generic product entered the
19 market.

20 51. In late June 2011, Watson Labs prevailed with respect to claim construction of the
21 ’529 patent. As the Patent Case Management Judicial Guide notes: “The construction of patent
22 claims plays a critical role in nearly every patent case. It is central to evaluation of infringement
23 and validity, and can affect or determine the outcome of other significant issues such as
24 unenforceability, enablement, and remedies.”

25 52. Shortly after the adverse claim construction decision, Endo filed a separate federal
26 court action against Watson Labs alleging that its generic product infringed three additional
27 patents that Endo had subsequently acquired—U.S. Patent Nos. 5,741,510 (the “’510 patent”),
28 6,096,333 (the “’333 patent”), and 6,096,334 (the “’334 patent”). Of these three patents, Endo

1 listed only the '510 patent in the Orange Book. No 30-month stay resulted from this later patent
2 litigation.

3 53. A six-day trial on the '529 patent infringement claims occurred in February 2012.
4 Coming out of that trial, Watson was confident in its litigation position.

5 **C. Endo paid Watson to abandon its patent challenge and refrain from**
6 **competing until September 2013**

7 54. On May 28, 2012, Endo and Watson settled both Lidoderm patent litigations (“the
8 Lidoderm Agreement”) before a final decision was issued in either case. [REDACTED]

9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

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

25 56. Watson could not have obtained the No-AG Payment or the Free Product
26 Payment even by prevailing in the patent infringement litigations with Endo.

27 **1. The No-AG Payment**

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

8 58. The No-AG Payment was extremely valuable to Watson. Because of eligibility
9 for first-filer exclusivity, the No-AG Payment ensured that Watson would not face generic
10 lidocaine patch competition for at least 180 days—and up to 7½ months—after its launch.

11 59. A substantial portion of this value from the No-AG Payment directly benefitted
12 Watson Pharma. When Watson launched generic Lidoderm in September 2013, significant
13 quantities of Watson’s generic product were sold through Anda, Inc., Watson Pharma’s wholly-
14 owned distribution subsidiary. [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

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

22 **2. The Free Product Payment**

23 61. As part of the Lidoderm Agreement, Endo agreed to provide \$12 million worth
24 of branded Lidoderm product monthly from January through August 2013 to Watson Pharma
25 through Anda, Inc. The product—worth a total of \$96 million—was free to Watson: Watson paid
26 Endo nothing for the branded product received under the Lidoderm Agreement. Endo further
27 agreed to provide up to \$144 million more in free branded Lidoderm in 2014 and 2015 if the
28 FDA did not approve Watson’s generic Lidoderm application. As stated in the Lidoderm

1 Agreement, Endo provided this free branded product to Watson as “a good-faith, bargained-for-
2 resolution of the claims at issue in the Litigation.” Even accounting for contributions from
3 Teikoku, Endo’s cost of providing the free branded Lidoderm product to Watson was roughly
4 \$85 million.

5 62. Although the free branded product was provided to Anda, Inc., the true
6 beneficiary was Watson Pharma. [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 **D. Endo’s payment to Watson is large**

10 63. The payment to the Watson entities under the Lidoderm Agreement is large. The
11 total value of Endo’s expected payment to Watson, including the No-AG Payment and the Free
12 Product Payment and discounting any royalties Watson paid to Endo, was at least \$250 million.

13 64. Endo’s commitment to refrain from selling an authorized generic for 7½ months
14 and to forgo the profits from authorized generic sales that it would have made during that period
15 resulted in hundreds of millions in gain for Watson at a substantial cost to Endo. Endo’s
16 commitment to refrain from selling an authorized generic would substantially increase Watson’s
17 expected generic Lidoderm revenues by allowing Watson to capture all generic Lidoderm sales,
18 instead of splitting these sales with Endo’s authorized generic. Additionally, as the only seller of
19 generic Lidoderm, Watson could charge up to 33% more than if it faced competition from an
20 authorized generic. In May 2012—the same month it entered into the Lidoderm Agreement—
21 Watson prepared several forecasts projecting Watson’s revenues and profits from generic
22 Lidoderm sales. Based on these forecasts, Watson could expect to earn at least \$214 million
23 more in generic Lidoderm revenues during its first six months on the market if it did not face
24 generic competition from an Endo authorized generic. Extending the effects of the no-AG
25 commitment to the full 7½ months granted under the Lidoderm Agreement increases the value to
26 at least \$260 million.

27 65. The Free Product Payment was worth more than \$90 million in additional
28 compensation to Watson. Watson anticipated that it would sell the free branded product to

1 customers at the prevailing market price, which was approximately 4% to 5% lower than the
2 contemporaneous brand wholesale acquisition cost (commonly referred to as “WAC”). Thus, for
3 the \$96 million of free branded product that Endo would supply to Watson Pharma through
4 Anda, Inc. in 2013, Watson Pharma could expect to profit by \$91.2 to \$92 million. Because
5 Watson Pharma did not have any direct costs for the free branded product, its entire revenues
6 from those sales were profit.

7 66. Any royalty Watson paid to Endo on Watsons’s generic sales would not offset
8 Endo’s payment to Watson. Based on Watson’s contemporaneous forecasts, its royalty payments
9 to Endo would only amount to approximately \$101 million, compared to Endo’s total payment in
10 excess of \$350 million.

11 67. Endo’s payment far exceeds any reasonable measure of avoided litigation costs in
12 the parties’ underlying patent litigation. The settlement occurred late in the litigation, after a six-
13 day trial and post-trial briefing. Endo already had spent around \$11.5 million on the litigation.
14 Any remaining litigation costs from either Lidoderm patent suit would be a small fraction of
15 Endo’s total payment.

16 68. Endo’s payment was designed to, and did, induce Watson to abandon the
17 Lidoderm patent challenge and agree to refrain from marketing its generic Lidoderm product
18 until September 2013. Watson’s decision to settle was driven not by the strength of Endo’s
19 patent protection for Lidoderm, but by the large payment Endo made to Watson.

20 69. Indeed, Endo’s payment exceeded the amount Watson projected to earn by
21 launching its generic version of Lidoderm. Based on internal forecasts prepared around the time
22 of settlement, Watson would earn at least \$100 million more from the Lidoderm Agreement
23 payment (even accounting for the royalty payments it would make to Endo) than it would earn
24 by launching generic Lidoderm immediately following FDA approval in 2012.

25 70. Endo was nonetheless willing to make the large payment to Watson because the
26 September 15, 2013 entry date would ensure that Endo could maintain monopoly prices for
27 Lidoderm throughout that period.

28 **E. Endo’s large payment is not justified**

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

5 78. The data available since the entry of Watson's generic version of Lidoderm
6 confirm the unique competitive impact of such entry on Lidoderm sales and prices. When
7 Watson entered with its generic product, Endo reduced the price of branded Lidoderm as much
8 as 40% in an effort to retain lidocaine patch sales. Nonetheless, within three months, Watson's
9 generic product had captured over 70% of the lidocaine patch unit sales.

10 79. If Endo already were facing robust competition to Lidoderm, then the entry of
11 generic competition to Lidoderm would not erode the sales volume of branded Lidoderm or the
12 price of lidocaine patches so rapidly and dramatically.

13 80. In addition, other drugs used to treat PHN have not meaningfully constrained
14 Endo's pricing or sales of Lidoderm. Between 2008 and 2013, Endo steadily increased its
15 Lidoderm WAC from approximately \$169 to \$260 per box of 30 patches. Over that same period,
16 however, Endo's unit sales of Lidoderm in the United States remained largely stable, fluctuating
17 between 1.5 and 2.0 million boxes quarterly. During that same period, the entry of new branded
18 products approved to relieve pain associated with PHN, such as Qutenza, Horizant, and Gralise,
19 had no discernible impact on Lidoderm prices or unit sales.

20 81. Moreover, because of its unique characteristics, Lidoderm is not reasonably
21 interchangeable with other medications used to relieve pain associated with PHN. Unlike other
22 PHN treatments, Lidoderm is a topical treatment that can be used at home and applied directly to
23 the skin on the affected area. While other drug therapies, such as anticonvulsants and
24 antidepressants, may be used in conjunction with lidocaine patches to improve results, they are
25 not viewed by physicians as substitutes. As the head of Endo's Pain Management business
26 explained: "Lidoderm was unique in the attributes that it presents to a physician and to a patient
27 as they're seeking a therapy . . . [T]here really is not another product that is exactly like
28 Lidoderm."

1 82. Before September 2013, Endo consistently held a 100% share of the relevant
2 market for lidocaine patches.

3 83. Substantial barriers to entry exist in the lidocaine patch market. Potential new
4 branded drug competitors need to conduct expensive clinical trials and obtain FDA approval.
5 Potential sellers of generic lidocaine patches also face substantial barriers to entry, including the
6 need to obtain FDA approval, costly specialized equipment and facilities to manufacture the
7 patches, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a
8 patent infringement lawsuit.

9 **B. Watson's monopoly power concerning generic lidocaine patches**

10 84. Watson exercised monopoly power in the relevant market of generic lidocaine
11 patches approved by the FDA for sale in the United States from September 2013 until Endo
12 began selling an authorized generic in May 2014. While numerous other drugs are used to relieve
13 pain associated with PHN (including branded Lidoderm), there is substantial evidence of
14 Watson's monopoly power throughout the relevant time period. Both Endo and Watson
15 predicted that generic lidocaine patch prices would fall considerably upon entry of the second
16 generic product, with no corresponding effect on the price of the branded product.

17 85. The data available since the entry of Endo's authorized generic version of
18 Lidoderm confirm the unique competitive impact of such entry on generic Lidoderm sales and
19 prices. By September 2014, Endo's authorized generic product had captured over 40% of generic
20 lidocaine patch unit sales, and authorized generic competition had lowered the average price of
21 generic lidocaine patches by more than 16%. Endo's efforts to discount the branded product had
22 no comparable effect on generic prices.

23 86. If Watson were already facing robust competition to its generic lidocaine patch,
24 then the entry of Endo's authorized generic version of Lidoderm would not erode the sales
25 volume of Watson's generic lidocaine patch or the price of lidocaine patches so rapidly and
26 dramatically.

27 87. In addition, although a branded product is therapeutically equivalent to its generic
28 counterpart, a unique competitive dynamic exists between generics. Typically, retail pharmacies

1 stock the branded product plus one generic version. Thus, while the brand company can expect
2 its product to be available at every pharmacy, generic companies must compete against one
3 another to be a pharmacy's primary generic supplier. Price is the primary mechanism of such
4 competition. Consequently, entry of additional generic competitors drives down the average
5 generic price, often to a fraction of the brand's pre-generic-entry price.

6 88. The initial price offered by the first generic entrant is typically a percentage off
7 the brand's list price (or WAC). But after the initial generic sales, any correlation between the
8 prices of the branded product and the generic products generally dissipates. Branded prices often
9 rise after generic entry as brand companies extract additional profits from those patients who are
10 not price sensitive and continue to buy the branded product, while generic prices fall as more
11 generic products come to market. The head of Endo's Pain Management business summarized
12 this dynamic as follows: "Nobody considers an average price of brand plus generic because they
13 operate in a different dynamic." Instead, "generic pricing tend[s] to be a function of how many
14 competitive players are there in the generic market."

15 89. Potential sellers of generic lidocaine patches face substantial barriers to entry,
16 including obtaining FDA approval, costly specialized equipment and facilities to manufacture the
17 product, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a
18 patent infringement lawsuit.

19 90. Before May 2014, Watson held a 100% share of the relevant market for generic
20 lidocaine patches.

21 VIII. Harm to Consumers and Competition

22 A. The Lidoderm Agreement eliminated the risk of generic competition for 23 more than one year

24 91. By impeding generic competition, Endo and Watson's conduct denied consumers
25 and other purchasers of Lidoderm access to AB-rated generic versions of Lidoderm that would
26 offer the same therapeutic benefit as branded Lidoderm, but at a lower price.

27 92. The agreement between Endo and Watson precluding Watson from launching a
28 generic version of Lidoderm until September 2013 harmed competition and consumer welfare by

1 eliminating the risk that Watson would have marketed its generic version of Lidoderm before
2 September 2013. Through their agreement, Endo eliminated the potential that: (1) Endo would
3 have agreed to settle the patent litigation on terms that did not compensate Watson, but provided
4 for generic entry earlier than September 2013; or (2) Watson would have otherwise launched its
5 generic Lidoderm before September 2013, whether or not patent litigation was still pending.

6 93. Before the Lidoderm Agreement, Watson was preparing to launch its generic
7 lidocaine patch as early as FDA approval, which it received in August 2012. Watson did not plan
8 to wait until an appeals court decision in patent litigation before launching its generic product.
9 Watson's generic entry would have quickly and significantly reduced Endo's market share,
10 promoted economic efficiency, and led to significant price reductions for lidocaine patches.
11 Indeed, when Watson ultimately launched its generic version of Lidoderm in September 2013,
12 Endo immediately responded by providing bigger discounts to retain Lidoderm's preferred
13 position on certain drug formularies.

14 94. Watson abandoned its generic entry plans because it received a share of Endo's
15 monopoly profits in the form of the No-AG Payment and the Free Product Payment. Without the
16 large payment, Watson would have launched its generic version of Lidoderm prior to September
17 2013.

18 95. Entry of Watson's generic product would have given consumers the choice
19 between branded Lidoderm and lower-priced generic substitutes for Lidoderm. Many consumers
20 would have chosen to purchase the lower-priced generic version instead of higher-priced branded
21 Lidoderm. In its contemporaneous forecasts, Endo predicted its Lidoderm revenues would
22 decrease by at least \$500 million during the first year after generic entry. As a result of this
23 generic competition, consumers would have saved hundreds of millions of dollars. By entering
24 into their anticompetitive agreement, Endo and Watson have shared additional monopoly profits
25 at the expense of consumers.

26 96. Absent an injunction, there is a cognizable danger that Endo and Watson will
27 engage in similar violations causing future harm to competition and consumers. Defendants
28 knowingly entered into and carried out a collusive anticompetitive scheme to preserve and share

1 Endo's monopoly profits. Each did so conscious of the fact that this agreement would greatly
2 enrich them at the expense of consumers.

3 97. Defendants have the incentive, opportunity, and demonstrated interest to continue
4 to enter other reverse-payment agreements in the future. Endo and Watson each continue to
5 develop and manufacture pharmaceutical products. Defendants are regularly involved in
6 multiple patent litigations relating to different drugs. Any of these existing or future patent
7 litigations provides the incentive and opportunity to enter into another a reverse-payment
8 agreement.

9 98. In addition, Defendants have the demonstrated interest to continue to enter into
10 such agreements in the future. Indeed, both Endo and Watson have entered into similar reverse-
11 payment agreements, even after the U.S. Supreme Court's 2013 decision in *FTC v. Actavis*.
12 These agreements include arrangements in which the payment is in the form of: (1) a business
13 transaction entered at or around the same time as the patent litigation settlement (serving a
14 similar purpose as the Free Branded Payment); or (2) a no-AG commitment in which the brand
15 company commits not to sell an authorized generic product for some period of time.

16 99. Defendants obtained the full benefit of their unlawful agreement concerning
17 Lidoderm. They did not abandon or disavow the Lidoderm Agreement or any other reverse-
18 payment agreement following the Supreme Court's decision in *FTC v. Actavis*, which rejected
19 the near automatic immunity for reverse-payment settlements that some courts had erroneously
20 adopted. On the contrary, Endo and Watson maintain that their unlawful Lidoderm Agreement
21 was procompetitive.

22 **B. The Lidoderm No-AG Payment reduced competition for generic lidocaine**
23 **patches for 7½ months**

24 100. The Lidoderm Agreement further harmed competition and consumers by
25 eliminating competition for sales of generic lidocaine patches until May 2014.

26 101. Before the Lidoderm Agreement, Endo and Watson were potential competitors in
27 the sale of generic lidocaine patches. Indeed, Endo's authorized generic was the only potential
28 generic competition to Watson's generic lidocaine patch during the 180-day first-filer exclusivity

1 period for generic Lidoderm. Under the Hatch-Waxman Act, the FDA was prohibited by law
2 from approving any other generic version of Lidoderm until the 180-day exclusivity period had
3 expired or been forfeited. Endo, however, was legally entitled to market an authorized generic
4 version of its own Lidoderm product at any time, including during the first filer's exclusivity
5 period.

6 102. Before the Lidoderm Agreement, Endo was planning to launch an authorized
7 generic as soon as Watson launched its generic lidocaine patch. Under its agreement with
8 Teikoku, Endo had the exclusive right to sell an authorized generic version of Lidoderm in the
9 United States. Endo also had the financial incentive to do so. As soon as Watson entered with its
10 generic product, Endo could sell an authorized generic to compete for sales to generic lidocaine
11 users, while preserving branded Lidoderm sales for the minority of users who were willing to
12 pay more for the branded product. Endo estimated that it could make more than \$150 million in
13 net sales during the first year after generic entry by selling an authorized generic in competition
14 with Watson.

15 103. Under the Lidoderm Agreement, however, Watson acquired an exclusive field-of-
16 use license that prevented Endo from launching an authorized generic until May 2014. By
17 eliminating the potential competition between Endo's authorized generic and Watson's generic
18 version of Lidoderm, this acquisition substantially reduced competition in the market for generic
19 lidocaine patches.

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

27 105. Upon termination of the exclusive field-of-use license, Endo immediately
28 launched a Lidoderm authorized generic through its subsidiary, Qualitest. Competition from

1 Endo's authorized generic product caused the price of generic lidocaine patches to quickly fall
2 by 16% or more. This significant price reduction is consistent with Endo's and Watson's
3 forecasts as well as the empirical literature on the price effects of authorized generic competition.

4 106. The partially exclusive nature of Watson's license resulted in no cognizable
5 benefits to counteract the harm caused by the absence of competition from an authorized generic.

6 107. Endo's commitment not to compete with an authorized generic was not
7 reasonably related to achieving any cognizable benefits of a larger procompetitive venture.

8 108. Because of barriers such as FDA approval, entry by other firms would not occur
9 to deter or counteract the competitive effects of eliminating an authorized generic.

10 **Count I**

11 **Restraint of Trade – Against Endo, Watson Labs, Watson Pharma, and Allergan plc as a**
12 **Successor-in-Interest or Alter Ego of Watson Pharma**

13 109. Plaintiff re-alleges and incorporates by reference the allegations in all of the
14 paragraphs above.

15 110. The agreement between Endo and Watson that Watson would not compete by
16 marketing lidocaine patches until September 2013 constitutes an unfair method of competition in
17 violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

18 **Count II**

19 **Monopolization – Against Endo**

20 111. Plaintiff re-alleges and incorporates by reference the allegations in all of the
21 paragraphs above.

22 112. Endo's willful maintenance of its monopoly in the lidocaine patch market through
23 a course of anticompetitive conduct, including its entry into an unlawful agreement with Watson,
24 constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15
25 U.S.C. § 45(a).

1 **Count III**

2 **Restraint of Trade – Against Endo, Watson Labs, Watson Pharma, and Allergan plc as a**
3 **Successor-in-Interest or Alter Ego of Watson Pharma**

4 113. Plaintiff re-alleges and incorporates by reference the allegations in all of the
5 paragraphs above.

6 114. The agreement between Endo and Watson that Endo would not compete in the
7 market for generic lidocaine patches until May 2014 constitutes an unfair method of competition
8 in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

9 **Count IV**

10 **Unlawful Acquisition – Against Watson Labs, Watson Pharma, Allergan plc as a**
11 **Successor-in-Interest or Alter Ego of Watson Pharma, and Endo**

12 115. Plaintiff re-alleges and incorporates by reference the allegations in all of the
13 paragraphs above.

14 116. Watson’s acquisition of an exclusive field-of-use license from Endo substantially
15 lessened competition in the generic lidocaine patch market in violation of Section 7 of the
16 Clayton Act, 15 U.S.C. § 18.

17 **Prayer for Relief**

18 WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to
19 issue a permanent injunction against violations of the FTC Act and, in the exercise of its
20 equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by
21 Defendants’ violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C.
22 § 53(b), 15 U.S.C. § 26, and its own equitable powers, enter final judgment against Defendants
23 on Counts I, II, III, and IV, ordering and adjudging:

- 24 1. That the agreement between Endo and Watson violates Section 5(a) of the FTC Act,
25 15 U.S.C. § 45(a);
- 26 2. That Endo’s course of conduct, including its entry into an unlawful agreement with
27 Watson, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
- 28 3. That Watson’s acquisition of an exclusive field-of-use license from Endo violates

1 Section 7 of the Clayton Act, 15 U.S.C. § 18;

2 4. That Defendants are permanently enjoined from engaging in similar and related
3 conduct in the future, including, but not limited to entering into:

4 a. Agreements that, in form or substance, involve payment from the brand
5 company to the generic company and the generic company's agreement to
6 refrain from competing for some period of time; and

7 b. Agreements that, in form or substance, prevent, restrict, or disincentive the
8 brand company from competing with an authorized generic version of its
9 product for some period of time; and

10 5. That the Court grant such other equitable relief as the Court finds necessary,
11 including restitution or disgorgement, to redress and prevent recurrence of
12 Defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged
13 herein.

14
15 Dated: January 23, 2017

16 DAVID C. SHONKA
17 Acting General Counsel

Respectfully Submitted,

DEBORAH L. FEINSTEIN
Director
Bureau of Competition

18
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