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Attorneys for Plaintiff Federal Trade Commission

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ALLERGAN PLC,

ALLERGAN FINANCE LLC,

WATSON LABORATORIES, INC.,

ENDO INTERNATIONAL PLC,

and

ENDO PHARMACEUTICALS INC.,

Defendants.

Case No. 17-cv-00312

COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

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

I. Nature of the Case

1. This antitrust case challenges an anticompetitive reverse-payment agreement between Endo and Watson to obstruct lower-cost generic competition to Lidoderm, Endo's most important branded prescription drug product. In 2011, Endo generated more than $825 million from Lidoderm, a lidocaine patch, 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.

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

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

[1] For convenience, Endo Pharmaceuticals Inc. and Endo International plc will be collectively referred to in this Complaint as "Endo." Watson Laboratories, Inc. will be referred to as "Watson Labs." Allergan Finance LLC, which was known as Watson Pharmaceuticals, Inc. in 2012 when 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."

year, until September 2013. The payment to the Watson entities included two components. First, Endo guaranteed that Watson would receive supra-competitive 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. 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. Second, Endo agreed to provide Watson Pharma with branded Lidoderm patches valued at $96 million to $240 million "at no cost," which Watson Pharma's wholly-owned distribution subsidiary, Anda, Inc., could sell for pure profit. In total, Endo's payment to the Watson entities was worth at least $250 million.

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

II. Jurisdiction and Venue

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

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

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

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

9. Defendant Watson's acquisition of an exclusive field-of-use license constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

10. Each Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

III. The Parties

11. Plaintiff Federal Trade Commission ("FTC") is an independent administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces and to seek equitable monetary remedies.

12. Defendant 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.

13. Defendant Endo International plc is the parent company of 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 revenues in 2014. At the time of the anticompetitive Opana ER agreement challenged in this complaint, Endo Pharmaceuticals Holdings Inc. was the parent of Endo Pharmaceuticals Inc. By the time of the anticompetitive Lidoderm agreement challenged in this complaint, Endo Pharmaceuticals Holdings Inc. was doing business as Endo Health Solutions Inc. The corporate officers of the parent entity negotiated and approved the Opana ER and Lidoderm agreements and the president signed them. Through a series of name changes, acquisitions, and corporate restructurings, Endo Health Solutions Inc. is now doing business as Endo International plc.

14. Defendant Watson Laboratories, Inc. 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 anticompetitive agreement challenged in this complaint, Watson Labs was engaged in developing, manufacturing, marketing, and distributing branded and generic pharmaceutical products. Watson Labs signed the anticompetitive agreement concerning Lidoderm challenged in this complaint on behalf of the Watson entities. As of August 2016, Watson Labs is a subsidiary of Teva Pharmaceutical Industries Ltd.

15. Defendant Allergan Finance LLC (f/k/a Actavis Inc. and f/k/a Watson Pharmaceuticals, 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 anticompetitive agreement challenged in this complaint, Allergan Finance LLC was known as Watson Pharmaceuticals, Inc. and was engaged in developing, manufacturing, marketing, and distributing branded and generic pharmaceutical products, among other things. The corporate officers of Watson Pharma negotiated the anticompetitive agreement, including substantial provisions directly benefitting Watson Pharma, and Watson Pharma's chief legal officer signed the agreement. In this and other ways discussed in this complaint, Watson Pharma was a direct participant in, and beneficiary of, the unlawful conspiracy with Endo.

16. Defendant Allergan plc (f/k/a Actavis plc) is a for-profit Ireland corporation, with its 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. 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 York/New Jersey area and work [redacted] at the

New Jersey location, which Allergan 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.

IV. Background

A. Federal law facilitates approval of generic drugs

17. 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.

18. 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."

19. 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. § 314.53.

20. 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).

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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

27. 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. When a pharmacist fills a prescription written for a branded drug, these laws allow or require 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.

28. State substitution 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.

29. 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

30. 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.

31. 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.

32. 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.

33. 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 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.

V. Anticompetitive Conduct

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

34. 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.

35. Lidoderm is a transdermal lidocaine patch indicated for relief of pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles. 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.

36. 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.

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

38. Teikoku Pharma USA, Inc. owns the Lidoderm NDA, and its Japanese parent, Teikoku Seiyaku Co., Ltd (collectively with Teikoku Pharma USA, "Teikoku") manufactures Lidoderm. 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.

39. 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.

40. 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 to the product without sacrificing unit sales or revenues. Even accounting for other direct expenses that Endo allocated to selling and marketing Lidoderm, Endo's profit margin on Lidoderm net sales was substantial, typically ranging between [redacted] and [redacted].

41. Endo regularly increased its list price, or wholesale acquisition cost ("WAC"), for 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

42. Lidoderm's financial success drew the attention of several generic competitors. In November 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 U.S. patent No. 5,827,529 (the "'529 patent") 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.

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

44. 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 those patents expired on May 2, 2012.

45. Watson Labs was the first generic company to file an ANDA with a paragraph IV 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.

46. 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.

47. Because Endo 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.

48. While the patent litigation was pending, the Watson entities took significant steps to be ready to launch as soon as the FDA approved the 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.

49. 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.

50. 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.

51. In late June 2011, Watson Labs prevailed with respect to claim construction 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."

52. 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—U.S. Patent Nos. 5,741,510 (the "'510 patent"), 6,096,333 (the "'333 patent"), and 6,096,334 (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.

53. 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.

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

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

55. 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 agreed to pay the Watson entities through two separate components. First, Endo committed not to sell an authorized generic version of Lidoderm for up to 7½ months following Watson’s launch (“No-AG Payment”). Second, Endo 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”).

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

1. The No-AG Payment

57. 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.

58. 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.

59. 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 wholly-owned distribution subsidiary. [redacted]

60. 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

61. As part of the Lidoderm Agreement, Endo agreed to provide $12 million worth of branded Lidoderm product monthly from January through August 2013 to Watson Pharma through Anda, Inc. The product—worth a total of $96 million—was free to Watson: Watson paid Endo nothing for the branded product received under the Lidoderm Agreement. Endo 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 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 contributions from Teikoku, Endo's cost of providing the free branded Lidoderm product to Watson was roughly $85 million.

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

D. Endo's payment to Watson is large

63. The payment to the Watson entities under the Lidoderm Agreement is large. The total value of Endo'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.

64. 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. Endo'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'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.

65. 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 would supply to Watson Pharma 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.

66. Any royalty Watson paid to Endo on Watsons's generic sales would not offset Endo'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's total payment in excess of $350 million.

67. Endo's payment far exceeds any reasonable measure of avoided 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. Any remaining litigation costs from either Lidoderm patent suit would be a small fraction of Endo's total payment.

68. Endo'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's patent protection for Lidoderm, but by the large payment Endo made to Watson.

69. Indeed, Endo's payment 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.

70. Endo was 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.

E. Endo's large payment is not justified

71. Endo'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 in exchange for the Lidoderm Agreement payment worth hundreds of millions of dollars.

72. 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.

73. The purpose and effect of Endo'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's commitment to forgo profitable Lidoderm authorized generic sales for 7½ months and the provision of 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.

74. 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.

75. 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.

76. Moreover, Endo's payment to Watson was not reasonably necessary to achieve any purported procompetitive objective of the Lidoderm Agreement.

VII. Monopoly Power

A. Endo's monopoly power concerning Lidoderm

77. Endo exercised monopoly power in the relevant market for lidocaine patches approved by the FDA for sale in the United States, through Watson's 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.

78. 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.

79. 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.

80. 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.

81. 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 Lidoderm."

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

83. 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.

B. Watson's monopoly power concerning generic lidocaine patches

84. 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.

85. 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.

86. 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.

87. 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.

88. The initial price offered by the first generic entrant is typically a percentage off the 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."

89. 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.

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

VIII. Harm to Consumers and Competition

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

91. By impeding generic competition, Endo 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.

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

eliminating the risk that Watson would have marketed its generic version of Lidoderm before September 2013. Through their agreement, Endo eliminated the potential that: (1) Endo 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.

93. 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 an 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.

94. 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.

95. 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 and Watson have shared additional monopoly profits at the expense of consumers.

96. Absent an injunction, there is a cognizable danger that Endo and Watson will engage in similar violations causing future harm to competition and consumers. 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.

97. Defendants have the incentive, opportunity, and demonstrated interest to continue to enter other reverse-payment agreements in the future. Endo 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.

98. In addition, Defendants have the demonstrated interest to continue to enter into such agreements in the future. Indeed, 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.* 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.

99. 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 near automatic immunity for reverse-payment settlements that some courts had erroneously adopted. On the contrary, Endo and Watson maintain that their unlawful Lidoderm Agreement was procompetitive.

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

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

101. 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.

102. 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.

103. 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.

104. As a result of Endo and Watson's conduct, competition between generic lidocaine patches was delayed for 7½ months until May 2014. Absent Endo's commitment not to compete with an authorized generic, Endo 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 and Watson shared additional profits at the expense of consumers.

105. 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.

106. 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.

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

108. 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.

Count I

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

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

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

Count II

Monopolization – Against Endo

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

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

Count III

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

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

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

Count IV

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

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

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

Prayer for Relief

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

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

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

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

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

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

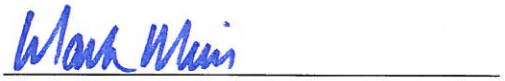
5. That the Court grant such other equitable relief as the Court finds necessary, including restitution or disgorgement, to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: January 23, 2017

Respectfully Submitted,

DAVID C. SHONKA
Acting General Counsel

DEBORAH L. FEINSTEIN
Director
Bureau of Competition



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